



United States
Department of
Agriculture



Cooperative State
Research, Education,
and Extension Service

Competitive
Programs

SBIR-05-1

Program Solicitation

Small Business Innovation Research Program

Fiscal Year 2005

Phase I Closing Date: August 31, 2004
Phase II Closing Date: February 3, 2005

Telephone: 202-401-4002
Internet: www.csrees.usda.gov/

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Please note that the text of the proposal should be prepared using at least 10 point font size regardless of whether it is single or double spaced.

The Program Solicitation, including all Application Forms, may be downloaded from the USDA SBIR Web Page: www.csrees.usda.gov/sbir/sbir.html

*****PLEASE READ*****

IMPORTANT CHANGES IN THE USDA SBIR FY 2005 PROGRAM SOLICITATION

Submission of Proposals - Proposals must be received at the USDA/CSREES/Proposal Services Unit by close of business, 5:00 p.m. Eastern Time, on the program deadline as indicated under section 6.1 of this program solicitation. **This year proposals may be scanned by CSREES into Portable Document Format (PDF). Applicants must adhere strictly to the proposal format outlined in section 3.3 of this solicitation. Failure to do so could negatively impact the display and subsequent review of your application.**

Proposals are encouraged that focus on problems dealing with bioterrorism (**directed at agriculture, the food supply, or rural communities**) and **homeland security of rural communities**. **Proposals addressing agriculturally-related manufacturing technologies are also encouraged.**

Recent changes in SBIR Legislation - The SBIR program has been reauthorized through 2008 (P.L. 106-554). The authorizing SBIR legislation requires two significant programmatic changes:

Commercialization Plan: All Phase II applications must include a succinct commercialization plan. See instructions for specific details (See Section 3.3(Q)).

Data Collection Requirement: Each Phase II applicant will be required to provide information for the Small Business Administration Tech-Net Database System (See Section 3.3(Q)).

Revised Topic Areas – Revisions have been made to the following topic areas: 8.3 Animal Production and Protection; 8.4 Air, Water and Soils; 8.5 Food Science and Nutrition; and 8.6 Rural and Community Development

New Topic Area – A new topic area dealing with **Animal Waste Management** has been added, and will be referred to as 8.11.

Duration of Phase I Projects: The duration of Phase I projects has been extended to 8 months (from May 1 to December 31).

**USDA'S PROGRAM SOLICITATION
SMALL BUSINESS INNOVATION RESEARCH
FISCAL YEAR 2005**

1.0 GENERAL PROGRAM DESCRIPTION

1.1 Introduction

The U.S. Department of Agriculture (USDA) invites science-based small business firms to submit research proposals under this program solicitation entitled "Small Business Innovation Research Program, Fiscal Year 2005." Firms with strong scientific research capabilities in any of the topic areas described in section 8.0 are encouraged to participate. USDA will support high-quality research or research and development (R&D) proposals containing advanced concepts related to important scientific problems and opportunities that could lead to significant public benefit if the research is successful.

Objectives of the Small Business Innovation Research (SBIR) program include stimulating technological innovation in the private sector, strengthening the role of small businesses in meeting Federal research and development needs, increasing private sector commercialization of innovations derived from USDA-supported research and development efforts, and fostering and encouraging participation by women-owned and socially and economically disadvantaged small business firms in technological innovation. Questions of a general nature about this SBIR solicitation should be directed to one of the following SBIR National Program Leaders:

Dr. Charles F. Cleland

Dr. William Goldner

Dr. S. Suresh Sureshwaran

Dr. Peter Burfening

via the following means: overnight courier (not U. S. Postal Service)

SBIR Program
U.S. Department of Agriculture
800 9th Street, SW
Suite 2312
Washington, D.C. 20024
Telephone: (202) 401-4002
Facsimile: (202) 401-6070
E-mail: SBIR@csrees.usda.gov

1.2 Three-phase Program

NOTE: This program solicitation is primarily for the preparation and submission of Phase I proposals. However, the solicitation is also applicable for those preparing Phase II proposals, for it contains the necessary forms for proposal submission, delineates the evaluation criteria that will be used, and provides other relevant information. More detailed guidance on Phase II proposal preparation will be provided by the SBIR Program, in a letter that is sent out in the fall of each year to Phase I awardees.

This program solicitation is issued pursuant to the Small Business Innovation Development Act of 1982, Pub. L. No. 97-219, as amended (15 U.S.C. 638) and Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Pub. L. No. 99-591, 100 Stat. 3341. This program is administered by the Cooperative State Research, Education, and Extension Service (CSREES) of the USDA.

This program is subject to the provisions found at 7 CFR Part 3403. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of grant projects.

The program will be carried out in three separate phases. Phase I is to determine the scientific or technical feasibility of ideas submitted by applicants on research topic areas described in section 8.0 of this solicitation with each award ranging up to \$80,000 for a period normally not to exceed 8 months. However, longer grant periods, up to 18 months, may be considered. (See section 4.2(E).) The Phase I proposal should concentrate on research which will significantly contribute to **proving the scientific or technical feasibility** of the approach or concept and which would be a prerequisite to further USDA support in Phase II.

Phase II awards will be made during fiscal year (FY) 2005 to firms with approaches that appear sufficiently

promising as a result of Phase I studies with each award ranging up to \$300,000 for a period normally not to exceed 24 months. **Only those small businesses previously receiving Phase I awards in either FYs 2003 or 2004 are eligible to submit Phase II proposals in FY 2005. Please note, however, that for each Phase I project funded, the awardee may apply for a Phase II award only once. Proposals for Phase II normally may only be submitted to the Federal agency from which the Phase I award was received.**

Phase I awardees in FY 2004 who are unable to submit Phase II proposals for valid reasons during the FY 2005 funding cycle, will be eligible to apply for Phase II support no later than the FY 2006 funding cycle. One reason for not submitting the Phase II proposal during the FY 2005 funding cycle would be one which precludes completion of the Phase I project within the designated award period. In such instances, the awardee must request in writing, prior to the end of the Phase I grant period, a no-cost extension from the Authorized Departmental Officer, outlining the circumstances which prevent completion of the project. Once the no-cost extension request is approved, any remaining Federal funds may be expended on the project in accordance with the approved budget within the extended award period.

Phase II is the principal research or research and development effort and will require a more comprehensive application, outlining the proposed effort in detail. At the appropriate time, the SBIR Program will send a letter to all eligible Phase I awardees requesting Phase II proposals. The letter will provide instructions for preparing Phase II proposals and a deadline date (normally early February of each year) for submitting applications. USDA recognizes that Phase II awards may not be sufficient in either dollars or time for the firm to complete the total research and development required to bring the project results to commercialization in the market place. Therefore, completion of the research under these circumstances may have to be carried into Phase III. The required Commercialization Plan should address this possibility.

See subsection 5.1 for estimated number of FY 2005 Phase I and Phase II awards and their established dollar limit.

The purpose of Phase III is to stimulate technological innovation and the national return on investment from research through the pursuit of commercialization objectives resulting from the USDA-supported work carried out in Phases I and II. No Federal SBIR funds may be used to support Phase III projects. However, firms are

strongly encouraged to secure Phase III funding from their own resources or from other public and private sources of funds. Additionally, Phase III is to be conducted by the small business firm (including joint ventures and limited partnerships).

1.3 Follow-on Funding

In addition to supporting scientific research and development, another important goal of this program is to provide incentive and opportunity for small business firms to convert USDA-sponsored research to technological innovation in the private sector. All proposed research should have some potential commercial outcome, and Phase II applicants are encouraged to obtain a contingent commitment for non-SBIR follow-on funding to pursue further development of the commercial potential during Phase III. Government funding pays for research relating to Federal objectives (Phases I and II); non-SBIR (public or private) funding pays for development of commercial objectives (Phase III).

Obtaining follow-on financial commitment(s) is the responsibility of the applicant. USDA understands that any such commitment will likely be contingent upon the Phase II awardee attaining technical objectives that are mutually agreed upon between the small business firm and the provider of the follow-on funding. These objectives should be closely related to those delineated in the Phase II research proposal. The technical objectives should be clearly defined and measurable, and should be specified in the commitment agreement at the threshold level that would justify such an investment. The objectives do not have to be identical to those stated in the Phase II proposal, but they must be able to be accomplished within the scope of the proposed SBIR-funded research. Any letters or other forms of tentative commitment for follow-on Phase III funding from sources other than Federal SBIR Programs, will be considered.

Phase I proposals should contain a brief description of any potential commercial application(s) and whether or not the small business firm will attempt to secure follow-on, non-SBIR funding to pursue the commercial development of the expected products from the proposed research. In order for Phase II applicants to receive consideration of follow-on funding during the review and evaluation process, a signed contingent commitment between the small business firm and the entity providing the follow-on financial support should be submitted with the Phase II application. While such commitment agreements are optional when submitting Phase II proposals, they will receive special consideration as a point of merit in the

review and evaluation process where proposals are evaluated as being of approximately equal technical merit. **The maximum value (in Phase II evaluation) will be given for a signed formal agreement with reasonable terms and funding equal to or in excess of the Federal investment requested in the Phase II proposal.** The agreement should set forth the specific amount of Phase III funds and should indicate the dates that such funds will be made available to the small business firm. Also, the agreement should contain a few specific technical objectives which, if achieved in Phase II, will make the commitment usable by the small business firm. The terms cannot be contingent upon the obtaining of a patent, due to the length of time this process requires.

The commitment may be in the form of venture capital or a package including venture capital, contract research and development, a joint venture, a research and development limited partnership, or other agreement with a non-SBIR source of funding. No amortization, repayment, or repurchase of commitment funds may be included during the Phase II period of performance.

Follow-on funding commitments will not be counted as part of the 50-page limit for Phase II proposals.

1.4 Eligibility

Each concern submitting a proposal must qualify as a small business concern for research or research and development purposes at the time of award (see definitions in section 2.0). In addition, the primary employment of the Program Manager must be with the small business concern at the time of award and during the conduct of the proposed research, unless otherwise approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator. Primary employment means that more than one-half of the Project Manager's time is spent in the employ of the small business. Primary employment with the small business applicant precludes full-time employment with another organization. This requirement applies to both Phase I and Phase II awards. Any deviations from this requirement must be approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator. While the Project Manager must work more than one-half of his/her time for the small business during the entire grant period, there is no minimal time requirement for what percentage of the Project Manager's time is spent working on the proposed research.

The small business concern must be the primary performer of the proposed research effort. In Phase I, a minimum of **two-thirds** of the research or analytical work, as determined by budget expenditures, must be performed by the proposing organization. For **Phase II awards**, a minimum of **one-half** of the research or analytical effort must be conducted by the proposing firm.

Also, for both Phase I and Phase II, the R/R&D work must be performed in the United States. However, based on a rare and unique circumstance, for example, a supply or material or other item or project requirement that is not available in the United States, agencies may allow that particular portion of the R/R&D work to be performed or obtained in a country outside of the United States. Approval by the funding agreement officer for such specific condition must be in writing.

Phase II proposals may be submitted only by Phase I Awardees.

1.5 Agency Contacts

Applicants and other interested parties are encouraged to contact the individual indicated for more information about each program area listed below. The mailing address for all of these program contacts is: Competitive Programs Unit; Cooperative State, Research, Education, and Extension Service; U. S. Department of Agriculture; STOP 2243; 1400 Independence Avenue, S. W.; Washington, D. C. 20250-2243.

8.1, Forests and Related Resources; 8.4, Air Water and Soils; and 8.7, Aquaculture: Dr. Charles Cleland; Telephone: (202) 401-6852; Fax: (202) 401-6070; Email: ccleland@csrees.usda.gov

8.2, Plant Production and Protection; 8.8, Industrial Applications; and 8.11, Animal Waste Management: Dr. William Goldner; Telephone: (202) 401-1719; Fax: (202) 401-6070; Email: wgoldner@csrees.usda.gov

8.3, Animal Production and Protection; and 8.10, Wildlife: Dr. Peter Burfening; Telephone: (202) 401-5823; Fax: (202) 401-6070; Email: pburfening@csrees.usda.gov

8.5, Food Science and Nutrition; 8.6, Rural and Community Development; and 8.9, Marketing and Trade: Dr. Siva Sureshwaran; Telephone: (202) 720-7536; Fax: (202) 401-6070; Email: ssureshwaran@csrees.usda.gov

2.0 DEFINITIONS

The following definitions apply for purposes of this solicitation:

2.1 Research or Research and Development

Research or research and development (R&D) means any activity which is:

- (A) A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- (B) A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- (C) A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

2.2 Small Business Concern

A small business concern means a concern which **on the date of award** of both the Phase I and Phase II funding agreements:

- (A) Is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor, and has a number of employees not exceeding 500 (full-time, part-time, temporary, or other) in all affiliated concerns. Business concerns, other than licensed investment companies or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661 et seq., are affiliates of one another when directly or indirectly (1) one concern controls or has the power to control the other; or (2) third parties (or party) control or have the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term “affiliates” is defined in greater detail in 13 CFR 121.103. The term “number of employees” is defined in 13 CFR 121.106. Business concerns include, but are not limited to, any individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except

that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture.

- (B) Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States.

2.3 Project Manager

The project manager is an individual designated by the applicant to provide the scientific and technical direction to the project described in a proposal.

2.4 Socially and Economically Disadvantaged Small Business Concern

A socially and economically disadvantaged small business concern is one:

- (A) Which is at least 51 percent owned by (i) an Indian tribe or a native Hawaiian organization, or (ii) one or more socially and economically disadvantaged individuals; and
- (B) Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

For purposes of this solicitation, a socially and economically disadvantaged individual is defined as a member of any of the following groups: Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Subcontinent Asian Americans, other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged, or any other individual found to be socially and economically disadvantaged by the SBA. See sections 103, Who is Socially Disadvantaged?, and 104, Who is Economically Disadvantaged?, of 13 CFR Part 124.

Note: The certification of socially and economically disadvantaged small business at item 2 of Form CSREES-667 is for statistical purposes only.

2.5 Women-owned Small Business Concern

Women-owned small business concern means a small business concern that is at least 51 percent owned by one or more women, or in the case of any publicly owned business, at least 51 percent of the stock is owned by women, and women control the management and daily business operations. “Control” as used in this context means exercising the power to make policy decisions. “Operate” as used in this context means being actively involved in the day-to-day management of the concern.

Note: Certification of women-owned small business at item 3 of Form CSREES-667 is for statistical purposes only.

2.6 United States

United States means the 50 States, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

2.7 Program Solicitation

A program solicitation is a formal request for proposals whereby a Federal agency notifies the small business community of its research or R&D needs and interests in broad and selected areas as appropriate to the agency, and requests proposals from small business concerns in response to these needs and interests. Announcement in the Federal Register or Governmentwide point of entry (<http://www.fedbizopps.gov>) are not considered an SBIR Program Solicitation.

2.8 Subcontract

A subcontract is any agreement, other than one involving an employer-employee relationship, entered into by an awardee of a funding agreement calling for supplies or services for the performance of the original funding agreement..

2.9 Funding Agreement

A funding agreement is any contract, grant, or cooperative agreement entered into between any Federal agency and any small business concern for the performance of experimental, developmental or research work, including products or services, funded in whole or in part by the Federal Government.

2.10 Commercialization

Commercialization is defined as the process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to Government or commercial markets.

2.11 SBIR Technical Data

SBIR Technical Data is defined as all data generated during the performance of an SBIR award.

2.12 SBIR Technical Data Rights

SBIR Technical Data Rights are rights a small business concern obtains in data generated during the performance of any SBIR Phase I, Phase II, or Phase III award that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the Government receives a license.

3.0 PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

3.1 Proposal Requirements

This is a solicitation for Phase I research proposals on advanced concepts from small business firms which have strong research capabilities in the basic and applied sciences.

The proposed research must be responsive to one of the USDA program interests stated in the research topic area descriptions of this solicitation. The USDA does not prioritize between research topic areas or between different research objectives within a specific research

topic area. Thus, the specific research objectives proposed by applicants are investigator-initiated and not initiated by the USDA, and applicants are free to propose any research project that fits within one of the research topic areas listed in section 9.0. The same research can often be the basis for technological innovation, new commercial products, processes, or services which benefit the public. This is a desirable economic objective, and such proposals are encouraged.

Proposals must cover only scientific research activities.
A small business must not propose technical

assistance, demonstration projects, classified research, or patent applications. Many of the research projects supported by the SBIR program lead to the development of new products based upon the research results obtained during the project. However, projects that seek funding solely for product development where no research is involved, i.e., the funds are needed to permit the development of a product based on previously completed research, will not be accepted.

Literature surveys should be completed prior to the Phase I or Phase II submission of the proposal and should not be proposed as part of the R&D effort. Proposals that deal principally with developing proven concepts for commercial markets or scaling up previously developed prototypes for commercial production should not be submitted, since such efforts are considered the responsibility of the private sector and therefore are not supported by USDA. A proposal must be limited to only one research problem. The title of the proposal must be entered on the Proposal Cover Sheet, Form CSREES-667, of the application. The same proposal may not be submitted under more than one topic area. However, an organization may submit separate proposals under different topic areas, or different proposals under the same topic area under this solicitation. Where similar research is discussed under more than one topic area, the applicant should choose the topic area whose description is most relevant to the applicant's research concept. Applicants may respond to any of the topic areas listed under section 9.0. Research may be carried out through the construction and evaluation of a laboratory prototype, where necessary. Duplicate proposals will be returned to the applicant without review.

The purpose of a research proposal is to provide a written statement that contains sufficient information to persuade members of the research community who review the proposal and then advise the USDA SBIR professional staff that the proposed research is a sound approach to an important scientific question and is worthy of support under the stated USDA evaluation criteria (see section 4.0). The proposal should be self-contained and written with the care and thoroughness accorded papers for publication. Each proposal should be reviewed carefully by the applicant and by others knowledgeable on the subject to ensure inclusion of data essential for comprehensive evaluation.

3.2 General Content

This solicitation is designed to reduce the investment of time and cost to small business concerns in preparing

formal proposals. Those who wish to respond should submit a research proposal of **no more than 25 pages (50 pages for Phase II)**, including cover page, project summary page, budget pages, and all proposal-related enclosures or attachments unless otherwise stated.

The following items do not count as part of the 25-page limit for Phase I or 50-page limit for Phase II: 1) Table of Contents (see subsection 3.3 (C)); 2) Response to Previous Review (see subsection 3.3(D)); 3) Assurance Statement(s) (see subsection 3.3(O)); 4) National Environmental Policy Act Exclusions Form (see subsection 3.3(P)); 5) letters from consultants, subcontractors or cooperative research and development agreement (CRADA) cooperators (see subsection 3.3(H)); **vitae for these individuals, however, are part of the page limit**; 6) letter from a university describing the arrangement if university facilities are being used (see subsection 3.3(G)); 7) follow-on funding agreements for Phase II proposals (see subsection 1.3); 8) Commercialization Plan; or 9) documentation of multiple Phase II awards to be submitted with Phase I proposals if the applicant has received more than 15 Phase II awards during the preceding five fiscal years (see subsection 3.3(M)).

The text must be prepared on only one side of the page using standard size (8 1/2" x 11"; 21.6 cm x 27.9 cm) white paper, with margins not less than 2.5 cm all sides and **type at least 10 point font size regardless of whether it is single or double spaced.** In the interest of equity to all applicants, no additional attachments, appendixes, or references beyond the 25-page limitation for Phase I (50-page limitation for Phase II) will be considered in the proposal evaluation process, and proposals in excess of the page limitation will not be considered for review or award. In addition, supplementary materials, **revisions**, and/or substitutions **will not be accepted after the due date for proposals.**

It is not necessary to provide a lengthy discourse on commercial applications in the Phase I proposal except to discuss them briefly under subsection 3.3(E), as appropriate, as well as under subsection 3.3(J). The Phase I proposal must be principally directed at feasibility-related research or R&D on the specific topic chosen.

3.3 Proposal Format

The following instructions apply for both Phase I and II proposals, unless otherwise noted. **Phase II proposals may only be submitted by Phase I award winners as noted in section 1.2.**

This year proposals may be scanned by CSREES into Portable Document Format (PDF). Applicants must strictly adhere to the proposal format outlined in this section of the solicitation. The proposal must be assembled in the following order and failure to do so could negatively impact the display and subsequent review of your application.

Note: The application forms may be downloaded from the www.csrees.usda.gov/funding/sbir/sbir.html. The forms are available in Word, WordPerfect, and PDF format.

(A) Proposal Cover Sheet - Complete Form CSREES-667 and use it as page 1 of the proposal. All pages must be consecutively numbered. The original of the Proposal Cover Sheet must contain the pen-and-ink signatures of the proposed project manager and the authorized organizational official. A proposal which does not contain the required signatures may be returned to the proposing small business without review. All other copies of the proposal must also contain a proposal cover sheet but facsimile or photocopied signatures will be accepted. The title should be a brief (140-character-maximum), clear, specific designation of the research proposed. It will be used to provide information to Congress and also will be used in issuing press releases; it should not contain highly technical words. In addition, phrases such as "investigation of" or "research on" should not be used.

(B) Project Summary - Complete Form CSREES-668 and use it as page 2 of the proposal. The technical abstract, limited to 200 words, should include a brief description of the problem or opportunity, project objectives, and a description of the effort. Anticipated results and potential commercial applications of the proposed research also should be summarized in the space provided. Key words, to be provided in the last block on the page, should characterize the most important aspects of the project.

The information contained on Form CSREES-668, "Project Summary," of successful proposals will be published by USDA and, therefore, should not contain proprietary information.

(C) Table of Contents - A Table of Contents, itself unpaginated, should be placed immediately following the Project Summary, Form CSREES-668. This table should direct the reviewer to the

pages for all sections of the proposal, beginning with the Proposal Cover Sheet.

(D) Resubmitted Proposals (Phase I)- If you are submitting a proposal in which the project described was previously submitted to the SBIR program but not funded, state the proposal is a resubmission on Question 12 of the Proposal Cover Sheet, Form CSREES-667. The revised proposal should clearly indicate the changes that have been made in the project. A clear statement acknowledging comments of the previous review, indicating revisions, rebuttals, etc., is part of the evaluation criteria as noted in subsection 4.3(F). Proposals that are resubmissions **must** respond to the previous submission's panel summary on no more than one page, titled **"RESPONSE TO PREVIOUS REVIEW,"** which is to be placed directly after the Table of Contents. This section will not be counted within the page limitations of the proposal. (Refer to subsection 4.2(I) Initial Screening Criteria.)

(E) Technical Content - Begin the main body of the proposal on page 3 and include:

- (1) Identification and Significance of the Problem or Opportunity** - Clearly state the specific technical problem or opportunity addressed and its importance.
- (2) Background and Rationale** - Indicate the overall background and technical approach to the problem or opportunity and the part that the proposed research plays in providing needed results.
- (3) Relationship with Research or Research and Development**

Phase I - Discuss the significance of the Phase I effort in providing a foundation for the Phase II R&D effort. State the anticipated results of the approach if the project is successful. This should address: (a) the technical, economic, social, and other benefits to the Nation and to users of the results such as the commercial sector, the Federal Government, or other researchers; (b) the estimated total cost of the approach relative to benefits; and (c) any specific policy issues or decisions which might be affected by the results.

Phase II - Discuss the results of the Phase I project. Include a discussion of the overall

background of the Phase I project, a list of the Phase I technical objectives, a presentation of a detailed description of the Phase I results, a clear interpretation of the results, and conclusions as to the feasibility of the project. This section is where the Phase II applicant presents results from Phase I that establishes technical feasibility. Therefore, this section should provide an adequate discussion of Phase I results. The applicant should also state here the anticipated results of the proposed approach if the project is successful. **In Phase II proposals, this section should constitute a substantial portion of the total proposal.**

- (4) **Technical Objectives** - State the specific objectives of the research or research and development effort. For Phase I, include the technical questions needed to establish the technical feasibility of the proposed approach.
- (5) **Work Plan** - The work plan must provide an explicit, detailed description of the research or research and development approach. The plan should list the tasks to be performed, **provide details of the methodology that would be used to research each task**, including statistical analysis, if applicable, and indicate how and where the work will be carried out. The Phase I effort should attempt to determine the technical feasibility of the proposed concept. The work plan should be linked with the technical objectives of the research and the questions the effort is designed to answer. **This section should constitute a substantial portion of the Technical Content section of the proposal.**
- (6) **Related Research or Research and Development** - Describe significant research or R&D activities that are directly related to the proposed effort, including any conducted by the project manager or by the proposing small business concern, how the proposed effort expands on the related work, and any planned coordination with outside sources. **The applicant must persuade reviewers that he or she is aware of related research in the selected subject.** It is critical that the applicant make a convincing case that the proposed research builds upon previous research and, if

successful, will lead to the development of new technology or a substantial improvement of existing technology.

- (7) **References** - Provide a complete list of all references cited in the proposal. For each reference, provide the complete name for each author, the date of the publication, the full title of the article, name of the journal or book published and the page numbers. The references should be listed in alphabetical order using the last name of the first author.
- (F) **Key Personnel and Bibliography** - Identify key personnel of the small business concern and include information on their directly related education and experience or a current copy of their vitae. (For consultants and subcontractors, include this information under subsection 3.3 (H)). For each key person, provide a chronological list of the most recent representative publications in the topic area during the preceding five years, including those in press. List the authors (in the same order as they appear on the paper), the full title, and the complete reference as specified in subsection 3.3 (E)(7). Where vitae are extensive, efforts should be made to reduce them to one page by focusing on only the most relevant experience or publications in order to meet the proposal limitation.
- (G) **Facilities and Equipment** - Describe the types, location, and availability of instrumentation and physical facilities necessary to carry out the work proposed. Items of equipment to be purchased must be fully justified under this section. When purchasing equipment or a product under the SBIR funding agreement, the small business should purchase only American-made items whenever possible. **If university facilities are being used, there must be a letter in the proposal from the authorized organizational representative of the university describing the arrangement and testifying that the facilities will be subject to the exclusive use and control of the applicant.** These letters will not be considered a part of the page limitation.
- (H) **Outside Services** - Involvement of university or other outside personnel in the planning and research stages of the project as consultants or through subcontracting arrangements is permitted and may be particularly helpful to

small business firms that have not previously received Federal research awards. Establishment of a Cooperative Research and Development Agreement (CRADA) with a USDA laboratory or other Federal laboratory may also be beneficial to proposing firms. If the proposal involves outside consultants, subcontracts or involvement with a CRADA partner, these arrangements should be described in detail. Include a brief resume and listing of relevant publications for each consultant and subcontractor. **Proposals must include letters from proposed consultants, subcontractors or CRADA cooperators indicating their willingness to serve in order for such participation to be considered during the proposal review and evaluation process (see subsection 4.3(C) or 4.5(D), as appropriate).** These letters will not be considered a part of the page limitation.

- (I) **Satisfying the Public Interest** - Specify how the proposed research will satisfy one or more of the following objectives: (1) Develops sustainable agricultural production systems; (2) Protects natural resources and the environment; (3) Creates a safe, nutritious and affordable food supply; (4) Develops value-added food and non-food products from agricultural materials; (5) Enhances global competitiveness; and (6) Enhances economic opportunity and quality of life, especially for people in rural areas.
- (J) **Potential Post Application** -Phase I - Briefly describe the commercialization potential of the proposed research in Phase I. In addition, indicate whether there appears to be a potential use of the proposed research by the Federal Government. Include a brief description of the proposing company (e.g., date founded, number of employees) and its field of interest. What are the major competitive products in this field, and what advantages will the proposed research have over existing technology (in application, performance, technique, efficiency or cost).

Phase II - In Phase II commercialization potential is more important and thus a more extensive commercialization plan must be presented (see Section 3.3 (Q)).

- (K) **Current and Pending Support** - If an identical proposal, or one containing a significant amount of essentially equivalent work as the one submitted in response to this solicitation, has

been previously funded or is currently funded, pending, or about to be submitted to another Federal agency or to USDA in a separate action, the applicant must provide the following information:

- (1) Name and address of the agency(s) to which a proposal was submitted, or will be submitted, or from which an award is expected or has been received.
- (2) Date of actual or anticipated proposal submission or date of award, as appropriate.
- (3) Title of proposal or award, identifying number assigned by the agency involved, and the date the proposal was submitted or the award was received.
- (4) Applicable research topic area for each proposal submitted or award received.
- (5) Title of research project
- (6) Name and title of project manager for each proposal submitted or award received.

USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.

- (L) **Budget** - Complete Form CSREES-2004 only for the **phase under which you are currently applying**. (An applicant for Phase I funding should not submit both Phase I and Phase II budgets.) Please note the following in completing the budget: **A budget narrative with supporting detail for each budget category as noted in items (1) through (5) of this subsection must be included.** The narrative should be included on a separate sheet of paper and placed immediately behind Form CSREES-2004. A separate Form CSREES-2004 must be submitted for any subcontract included in "All Other Direct Costs" of the applicant's budget form.

- (1) **Salaries and Wages** - Indicate the number and kind of personnel for whom salary support is sought, including job tasks. For key personnel, also indicate the number of work months of involvement to be supported with USDA funds (see section labeled "CSREES Funded Work Months"), and explain how the level of compensation was established, e.g., the hourly rate of pay, the monthly rate of pay, or the yearly rate of pay.

- (2) **Equipment** - Performing organizations are expected to have appropriate facilities, suitably furnished and equipped. However, funding for items of equipment may be requested provided that they are specifically identified with the dollar amount and adequately justified (see item (G) of this section), **but such requests should normally not exceed 10% of the budget for Phase I.** This limit does not apply to Phase II budgets, however, **Phase II equipment purchases must be adequately justified.** Equipment is defined as an article of nonexpendable, tangible personal property having a useful life of more than 1 year and an acquisition cost of \$5000 or more per unit. However, consistent with recipient policy, lower limits may be established. **Vesting** of title to equipment purchased with funds provided under an SBIR funding agreement will be **determined by USDA. Awardees should plan to lease expensive equipment.** The inclusion of equipment will be carefully reviewed with respect to need and appropriateness for the research proposed.
- (3) **Materials and Supplies** - The types of expendable materials and supplies required should be indicated in general terms with estimated costs.
- (4) **Travel** - The type and extent of travel and its relationship to the project should be specified. Funds may be requested for field work or for travel to professional meetings. Requests for foreign travel are discouraged but may be approved (e.g., proposals submitted to the Marketing and Trade topic area that are focused on export issues) based on the justification provided in the proposal. In the budget narrative, for travel, provide the purpose, the destination, method of travel, number of persons traveling, number of days, and estimated cost for each trip. If details of each trip are not known at the time of proposal submission, provide the basis for determining the amount requested.
- (5) **All Other Direct Costs** - Other anticipated direct costs not included above should be itemized. Examples include, but are not limited to, subcontracts and consultants. See subsections 3.3(H) for required documentation associated with subcontracts

and consultants. A budget and budget narrative stating sub contractual and consulting costs and the rationale for the amount of the costs is required.

- (6) **Fee** - A reasonable fee, not to exceed 7% of total Federal funds awarded (.07527 of total Direct and F&A/Indirect Costs) is permitted under this program solicitation but applicants are encouraged to minimize fee requests due to the small amount of funds available. **All fees are subject to negotiation with USDA.** If a fee is requested, the amount should be indicated in block M., "Other," on the budget sheet.
- (7) **Indirect Costs** - If available, the current rate negotiated with the cognizant Federal negotiating agency should be used. Indirect costs may not exceed the negotiated rate. If a negotiated rate is used, the percentage and base should be indicated in the space allotted under item K. on the budget sheet. If no rate has been negotiated, a reasonable dollar amount in lieu of indirect costs may be requested, which will be subject to approval by USDA. In the latter case, if a proposal is recommended for funding, an indirect cost rate proposal must be submitted to support the amount of indirect costs requested. CSREES will request an indirect cost rate proposal and provide instructions, as necessary. An applicant may elect not to charge indirect costs and, instead, use all grant funds for direct costs. If indirect costs are not charged, the phrase "None requested" should be written in this space.
- (8) **Cost Sharing** - Cost sharing is permitted for proposals under this program solicitation; however, cost sharing is not required nor will it be an evaluation factor in considering the competitive merit of proposals submitted.

(M)Documentation of Multiple Phase II Awards

- (1) A small business firm that submits a proposal for a funding agreement for Phase I of an SBIR Program and that has received more than 15 Phase II SBIR awards during the preceding 5 FYs must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards. In

addition, the documentation must include the name of the awarding agency, date of award, funding agreement number, amount, topic or subtopic title, follow-on agreement amount, source and date of commitment and current commercialization status for each Phase II award. (This information will not be counted toward the 25-page limitation.); and

- (2) USDA shall collect and retain the information submitted under subparagraph (M)(1) at least until the General Accounting Office submits the report required under section 105 of the Small Business Research and Development Enhancement Act of 1992.

(N) Certifications Regarding Non-Delinquency on any Federal Debt, Drug-free Workplace, Debarment and Suspension, and Lobbying -

Certifications are accomplished by signing Form CSREES-667, Proposal Cover Sheet. (For instructions see subsection 5.11(A) through (D).)

- (O) Assurance Statement(s) -** See subsection 5.8. Complete Form CSREES-2008 as appropriate. This form will not be considered a part of the page limitation.

- (P) National Environmental Policy Act Exclusions Form (NEPA) -** See subsection 5.11(E). Complete Form CSREES-2006 and place it at the end of the proposal. This form will not be considered a part of the page limitation.

- (Q) Commercialization Plan (Phase II) -** A succinct commercialization plan, not to exceed 10 pages, must be attached as a separate document to the Phase II proposal. This plan will not be considered a part of the 50-page limitation for the Phase II proposal. The commercialization plan should provide information that directly relates to Phase III. The commercialization plan should provide a description of each of the following areas:

- (1) Introduction of the SBIR Project and Expected Outcomes: Describe, in layperson's terms, the proposed project and its key technology objectives. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in the application;

- (2) Company Information: Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), and any current products/services that have significant sales. Indicate your vision for the future and how you will grow/maintain a sustainable business entity. Include a short description of the origins of the company.

- (3) The Market, Customer and Competition: Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will need to overcome in order to gain market/customer acceptance of your innovation. Briefly explain the plans you have for approaching your potential customers, i.e., your marketing and sales strategy. Describe the current competition and any potential competitors over the next several years.

- (4) Intellectual Property: Describe how you will protect the intellectual property that results from your innovation. Note any actions you may consider to attain at least a temporary competitive advantage.

- (5) Financing: How will you raise the necessary financing for Phase III commercialization? Show you have a plan for this funding in one or more of the following ways:

- (a) A letter of commitment for follow-on funding;
- (b) A letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exists;
- (c) A letter of support for the project and/or some in-kind commitment;
- (d) A specific plan that you have to take to secure Phase III funding. The progress of this plan must be commented on in the Phase II progress report.

Note: Data Collection Requirement - Phase II

(1) Each Phase II applicant will be required to provide information for the SBA Tech-Net Database System (<http://technet.sba.gov>). Following are examples of the data to be entered by applicants into Tech-Net:

- (a) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR award is made.
- (b) Revenue from the sale of new products or services resulting from the research conducted under each Phase II award;
- (c) Additional investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award;

(d) Update the information in the Tech-Net database for any prior Phase II award received by the small business concern. The small business concern may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award.

(2) Upon completion and submission of the termination report (see section 5.2), each Phase II awardee is required to update the appropriate information on the award in the Tech-Net database at the expiration of the award period and is requested to voluntarily update the information in the Tech-Net database annually thereafter for a minimum period of 5 years.

4.0 METHOD OF SELECTION AND EVALUATION CRITERIA

4.1 Introduction

All Phase I and II proposals will be evaluated on a competitive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by engineers or scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merits. The agency is under no obligation to fund any proposal or any specific number of proposals in any given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic. **Proposals received outside of the solicitation period or proposals not responding to research topic areas outlined in section 8.0 of this program solicitation are not eligible to be considered for a Phase I SBIR award and, hence, will be returned to the proposing small business firm without review.**

External peer reviewers will be used during the technical evaluation stage of this process. Selections will be made from among recognized specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals received. It is anticipated that these experts will be drawn from universities, Government, and non-profit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

Final decisions will be made by USDA based upon the ratings assigned by reviewers and consideration of other factors, **including the potential commercial application**, possible duplication of other research, any critical USDA requirements, program balance, budget limitations and, for Phase II proposals only, any follow-on funding commitment. There is no commitment by USDA to fund any particular proposal, to support any specific number of proposals in a given research topic area, or to make a specific number of awards under either Phase I or Phase II. USDA also may elect to fund several or none of the proposed approaches to the same topic. Care will be taken to avoid actual and potential conflicts of interest among reviewers. Evaluations will be confidential to USDA staff members, peer reviewers, and the proposed project manager, to the extent permitted by law.

4.2 Initial Screening Criteria

To avoid misunderstanding, applicants should be aware that proposals not satisfying all of the screening criteria may be returned to the proposing entity without review. Returned proposals may not be resubmitted (with or without revision) under this solicitation. The initial screening criteria are the following:

- (A) The proposing firm must qualify as a small business concern as defined in subsection 2.2.
- (B) The proposal must meet the General Content requirements as described in subsection 3.2.

- (C) Proposals must be limited to one research problem (see subsection 3.1).
- (D) The proposed budget must be within the dollar limit identified in subsection 1.2.
- (E) The proposed duration of Phase I projects should normally not exceed 8 months, except in special, justified circumstances, and the duration of Phase II projects should normally not exceed 24 months. Where a proposed research project requires more than 8 months to complete in Phase I, a longer grant period, not to exceed 18 months, may be considered. An applicant of a Phase I project with an anticipated duration beyond 8 months should specify and justify the length of duration in the proposal at the time of its submission to USDA in order for it to be considered.
- (F) Proposals must cover scientific research activities only (see subsection 3.1).
- (G) The proposed Phase I research must fall within a solicited topic area. (See section 8.0 for the listing of research topic descriptions.)
- (H) A proposal must contain adequate scientific/technical information to state clearly the research plan and objectives. USDA reserves the right not to submit for review any proposal which it finds to have insufficient scientific/technical information.
- (I) A resubmitted proposal must address concerns of the previous review panel. USDA reserves the right not to submit for review any proposal found not to be responsive to the previous review.
- (J) A proposal must adhere strictly to the format outlined in section 3.3 of this solicitation.

4.3 Phase I Evaluation Criteria

USDA plans to select for award those proposals offering the best value to the Nation. The primary evaluation criteria used by reviewers are listed below. Approximately equal consideration will be given to each criterion, **except for item (A) which will receive twice the value of any of the other items:**

- (A) **Scientific and Technical Feasibility:** Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and will they lead toward proving the technical feasibility of the approach or concept? Does the research plan offer an original and

innovative approach to the problem and sufficient detail to indicate how each research objective will be investigated? Can the research plan reasonably be completed in the requested grant period?

- (B) **Importance of the Problem:** Does the proposal provide sufficient justification for the importance of the problem and clearly indicate the anticipated commercial potential of the proposed research? Is the proposed project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3 (I)?
- (C) **Investigator and Resource Qualifications:** Is adequate bibliographic information provided to document that the project manager, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the project manager will work a minimum of 51 percent of his/her time for the small business firm during the period of the grant and that the small business firm will conduct a minimum of two-thirds of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study, their rates of pay, and any other budgetary information? Are adequate research facilities available that the small business firm either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?
- (D) **Budget:** Is the budget appropriate for the proposed research plan? Is sufficient budget detail, including subcontract, consultant and CRADA data, provided to indicate clearly how the funds would be utilized?
- (E) **Duplication:** Does the proposed research substantially duplicate any ongoing or previous research by the small business firm or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business firm or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?
- (F) **Resubmission:** If the proposal is a resubmission, did the applicant provide a "Response to Previous Review?" Were the responses to the previous year's panel summary

appropriate? (Refer to subsection 3.3(D), Proposal Format.)

- (G) Commercial Potential:** Applicant should describe previous commercialization of SBIR or other research. Applicants should indicate any second phase funding commitments from private sector or non-SBIR funding sources. Applicant should also indicate any other commercial potential factors.

Additional factors that will be considered in the review process are whether a proposal involves a CRADA with a USDA laboratory or is a resubmission. In the event that two or more proposals are of approximately equal merit, the existence of a CRADA with a USDA laboratory will be an important consideration. If one proposal is a resubmission, this will also be an important consideration.

4.4 Phase I Review Process

USDA uses confidential peer review as the basis for evaluating all Phase I proposals. There are separate review panels corresponding to each of the topic areas listed in Section 8.0. (The Plant Production and Protection topic area is subdivided into Biology and Engineering review panels). All reviewers are drawn primarily from universities, government, and non-profit research organizations. For each topic area a leading research scientist is appointed as a topic manager. In consultation with the SBIR program staff, this individual appoints a review panel. The review panel meets in Washington, D.C., to evaluate all proposals. Proposals are reviewed both by members of the review panel and by ad hoc reviewers with specific expertise appropriate for each proposal. The panel discusses each proposal carefully and then ranks the proposals. The panel rankings are used in determining which proposals are funded.

Considerable effort is made to ensure that the review process is confidential. All reviewers are instructed to handle all proposals in complete confidence. Under the reviewer's signature on the review sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and that no basis for a conflict-of-interest has been found."

Every effort is made to avoid even the appearance of a conflict-of-interest (COI). The USDA has very detailed rules on COI that are followed during the review process. If a panel member has a COI on a proposal,

he/she is excused from the panel meeting while the particular proposal is being discussed. USDA is committed to ensuring the review process is fair and is handled with confidence.

4.5 Phase II Evaluation Criteria

Only awardees in Phase I are eligible to participate and submit a Phase II proposal. This includes those awardees identified via a "novated" or "successor-in-interest" revised funding agreement. The primary evaluation criteria used by reviewers are listed below and except for item (B) are largely identical to those for Phase I. Approximately equal consideration will be given to each criterion, **except for items (A), (B) and (C) which will receive twice the value of any of the other items:**

- (A) Scientific and Technical Feasibility:** Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and appropriate for a two year research and development period? Does the research plan offer an original and innovative approach to the problem and sufficient detail to indicate how each research objective will be investigated?

- (B) Degree to Which Phase I Objectives were Met and Technical Feasibility Established:** Are the Phase I objectives clearly stated and Phase I results presented in sufficient detail to permit a reviewer to determine whether the objectives were fully met and technical feasibility clearly established?

- (C) Commercial Potential:** Does the Commercialization Plan (see Section 3.3(Q)) clearly indicate the commercial potential of the proposed research and provide adequate information on the company, the market that is being targeted, the potential customers, the competition, and the plans for protection of intellectual property? Applicant should describe previous commercialization of SBIR or other research. Applicant should indicate any second phase funding commitments from private sector or non-SBIR funding sources. Applicant should indicate any third-phase follow-on commitments for the subject of the research. Applicant should also indicate any other commercial potential factors.

- (D) Importance of the Problem:** Does the proposal provide sufficient justification for the importance of the problem? Is the proposed

project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3(I)?

(E) Investigator and Resource Qualifications: Is adequate bibliographic information provided to document that the project manager, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the project manager will work a minimum of 51 percent of his/her time for the small business firm during the period of the grant and that the small business firm will conduct a minimum of one-half of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study? Are adequate research facilities available that the small business firm either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?

(F) Budget: Is the budget appropriate for the proposed research plan? Is sufficient budget detail provided to indicate clearly how the funds would be utilized?

(G) Duplication: Does the proposed research substantially duplicate any ongoing or previous research by the small business firm or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business firm or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?

Additional factors that will be considered in the review process are whether a proposal involves a CRADA with a USDA laboratory or contains a follow-on funding commitment for Phase III. In the event that two or more proposals are of approximately equal merit, the existence of a CRADA with a USDA laboratory will be an important consideration. The existence of a follow-on funding commitment for continued development in Phase III will also be an important consideration. The value of any commitment will depend upon the degree of financial commitment made by non-Federal investors, with the **maximum value resulting from a signed**

agreement with reasonable terms for an amount at least equal to the funding requested from USDA in Phase II.

4.6 Phase II Review Process

USDA uses confidential peer review as the basis for evaluating all Phase II proposals. All reviewers are drawn primarily from universities, government, and non-profit research organizations. However, there are far fewer proposals at Phase II and a different process is used. There are no review panels. Instead, six to eight top experts for each proposal are contacted to secure their agreement to serve as an ad hoc reviewer. A proposal is not sent to a reviewer unless he/she agrees to review the proposal in strict confidence. In addition, under the reviewer's signature on the review sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and no basis for a conflict-of-interest has been found." The same COI rules used in the Phase I are used for Phase II and no individual is sent a proposal where even the appearance of a COI exists.

4.7 Notice to Applicants

Technical reviewers will base their conclusions and recommendations on information contained in the proposal. It cannot be assumed that reviewers are acquainted with any experiments referred to within a proposal, with key individuals, or with the small business firm itself.

After final decisions have been announced, a panel summary that briefly sets forth the main strengths and weaknesses of the proposal, plus written reviews of the proposal, will be sent to the proposed project manager. The reviews will not include the scores or the identities of the reviewers. Due to funding limitations and USDA's desire to support as many worthwhile projects as possible, it may be necessary for USDA to reduce the amount of an award below the amount requested by a small business (or to fund only certain objectives outlined in the proposal). Any significant changes will be discussed with the proposing firm, which may then be asked to submit a revised budget reflecting the reduced amount. In the event that this occurs, specific instructions will be provided to the applicant.

5.0 CONSIDERATIONS

5.1 Awards

USDA expects to make approximately 90 Phase I awards ranging up to \$80,000 each to small businesses in FY 2005, depending upon the availability of funds. Awards are expected to be made on or before May 1, 2005. USDA will announce the names of those concerns receiving awards, and successful Applicants will then normally have 6 months after awards are made to carry out their proposed Phase I effort.

USDA expects to make approximately 35 Phase II awards ranging up to \$300,000 each to previous USDA Phase I awardees, depending upon the results of the Phase I efforts, the scientific and technical merit of the Phase II proposal, and the availability of funds.

In accordance with the guidelines contained in 31 U.S.C. 6301-6308, and the authority contained in Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Public Law Number 99-591, 100 Stat. 3341, **all Phase I and Phase II awards will be issued as research grants.**

A reasonable fee, not to exceed 7% of total Federal funds awarded (.07527 of total direct and F&A/indirect costs) is permitted under this program solicitation but applicants are encouraged to minimize fee requests due to the small amount of funds available. All fees are subject to negotiation with USDA. If a fee is requested, the amount should be indicated in block M., "Other," on the budget sheet.

5.2 Reports

For both Phase I and Phase II an original and two copies of a brief interim progress report must be submitted at approximately the mid-point in the project. In addition, an original and two copies of a comprehensive final performance report must be submitted within 30 days following expiration of the Phase I grant and within 90 days following expiration of the Phase II grant. The report should include a single-page project summary as the first page. This summary should include the purpose of the research, a brief description of the research carried out, the research findings or results, and, in a final paragraph, potential applications (commercial or other) of the research. The balance of the report should include

a comparison of actual accomplishments with the goals established for the grant; the reasons for slippage if established goals were not met; estimates of technical feasibility; and additional pertinent information such as an explanation of cost over-runs or unexpectedly high unit costs. Also, identify all other recipients (public and private) of the research results documented in the Phase I or Phase II report. This report should be submitted to the SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

A final "Financial Status Report" (SF-269) is due within 90 days after the expiration date of the grant and should be submitted to the Funds Management Branch, Office of Extramural Programs at the address listed below, in accordance with instructions contained in Section 3015.82 of the Uniform Federal Assistance Regulations.

Funds Management Section
Office of Extramural Programs
Cooperative State Research, Education,
and Extension Service
U.S. Department of Agriculture
STOP 2298
1400 Independence Avenue, S.W.
Washington, D.C. 20250-2298
Telephone: (202) 401-4527

All Phase I and Phase II awardees are required to submit the AD-416 and AD-417 CRIS (Current Research Information System) report forms before a project can be awarded. In addition, the AD-421 report form has to be submitted at the conclusion of a Phase I project as a termination report. For Phase II the AD-421 report form is submitted after the first year as a progress report and at the end of the project as a termination report. Additional information about CRIS will be provided to all awardees prior to the start of their award.

5.3 Payment Schedules

Payments will be made by electronic funds transfer through the Department of Health and Human Services' Payment Management System (DHHS-PMS). Requests for payment should be in accordance with DHHS-PMS instructions. All questions relating to payments should be submitted to:

Funds Management Section
Office of Extramural Programs
Cooperative State Research, Education, and

Extension Service
U. S. Department of Agriculture
STOP 2298
1400 Independence Avenue, S. W.
Washington, D. C. 20250-2298
Telephone: (202) 401-4527
Facsimile: (202) 401-3481

Drawdown instructions will be sent to the awardee under separate cover. Payments shall be made according to the following schedule:

- a.** Aggregate payment requests of up to 50% of total award dollars will be honored during the first half of the project.
- b.** A mid-project payment request should accompany the progress report required in section 5.2 above. Upon acceptance of the performance report, up to an additional 35% of total dollars will be paid to the awardee.
- c.** The final 15% of total award dollars will be paid upon receipt and acceptance of the comprehensive final technical report required under section 5.2 above.

If the awardee is a sole proprietorship, funds awarded shall be deposited in a separate bank account and CSREES, through the funding agreement officer, shall be informed of the name and location of the bank. In addition, arrangements must be reached between the awardee and the bank of deposit of the award funds in accordance with the following: The account must be of a nature that permit the bank of deposit to return unused funds remaining in that account to CSREES in the event of the awardee's demise. However, CSREES shall not be named a joint owner of such an account, but rather as beneficiary. These arrangements must also be reported to CSREES through the ADO.

5.4 Proprietary Information

Information contained in unsuccessful proposals will remain the property of the applicant. The Government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information is provided by an applicant in a proposal, which constitutes a trade secret, proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law. This information must be clearly marked by the applicant with the term "confidential

proprietary information" and the following legend must appear on the title page of the proposal: "These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages ___ of this proposal."

Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration, without assuming any liability for inadvertent disclosure. The Government will limit dissemination of such information to within official channels.

USDA, by law, is required to make the final decision as to whether the information is required to be kept in confidence. Information contained in unsuccessful proposals will remain the property of the applicant. However, USDA will retain for one year one file copy of all proposals received; extra copies will be destroyed. Public release of information for any proposal submitted will be subject to existing statutory and regulatory requirements. The legislation reauthorizing the SBIR Program strengthened the protection of awardee firms relative to maintaining confidentiality of proprietary information for a period of four years after the end of the grant period. However, any proposal which is funded will be considered an integral part of the award and normally will be made available to the public upon request through the Freedom of Information Act, except for designated proprietary information.

The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary information is to be included, it should be limited, set apart from other text on a separate page, and keyed to the text by numbers. It should be confined to a few critical technical items which, if disclosed, could jeopardize the obtaining of foreign or domestic patents. Trade secrets, salaries, or other information which could jeopardize commercial competitiveness should be similarly keyed and presented on a separate page. Proposals or reports which attempt to restrict dissemination of large amounts of information may be found unacceptable by USDA.

5.5 Rights in Technical Data

Rights in technical data, including software developed under the terms of any funding agreement resulting from a proposal submitted in response to this solicitation, shall remain with the grantee. However, the Government shall have the limited right to use such data for Governmental purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project under which the data were generated. Effective at the conclusion of the four-year period, the Government shall retain a royalty-free license for Governmental use of any technical data delivered under the agreement, whether patented or not.

5.6 Copyrights

With prior written permission of the Authorized Departmental Officer, the grantee normally may copyright and publish (consistent with appropriate national security considerations, if any) material developed with USDA support. USDA receives a royalty-free license for the Federal Government and requires that each publication contain the following acknowledgment and disclaimer statement:

“This material is based upon work supported by the U.S. Department of Agriculture under Grant No. (awardee should enter agreement number here). Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the U.S. Department of Agriculture.”

The last sentence may be omitted from articles published in scientific journals.

5.7 Patents and Inventions

Allocation of rights to inventions shall be in accordance with 35 U.S.C. 202-206 and the Department of Commerce implementing regulations entitled “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements” at 37 CFR Part 401. These regulations provide that small businesses normally may retain the principal worldwide patent rights to any invention developed with USDA support. USDA receives a royalty-free license for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United

States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period to allow the grantee a reasonable time to file an initial patent application. Additional information may be obtained by contacting:

Mr. John Fado
Deputy Assistant General Counsel for Patents
U.S. Department of Agriculture
STOP 1415
1400 Independence Avenue, S.W.
Washington, D.C. 20250-1415

SBIR awardees must report inventions to the awarding agency within two months of the inventor’s report to the awardee. The reporting of inventions may be made through electronic submission to Interagency Edison. Specific instructions for invention reporting are contained in the agency’s terms and conditions, a copy of which can be provided upon request.

5.8 Research Involving Special Considerations

A number of situations frequently encountered in the conduct of scientific research require the submission of special information for a particular project. Since some types of research targeted for SBIR support have high probability of involving either recombinant deoxyribonucleic acid (DNA) molecules, human subjects at risk, or vertebrate animals, special instructions follow.

If the proposed research will involve either recombinant DNA molecules, human subjects at risk, or vertebrate animals, the proposal must so indicate by checking “Yes” in Item 11. of Form CSREES-667 and then completing Form CSREES-2008. Further, in the event that the project is funded, the applicant may be required to have the research plan reviewed and approved by the appropriate review board or committee. It is suggested that applicants contact local universities, colleges, or nonprofit research organizations which have established such reviewing mechanisms to have this service performed.

Guidelines to be applied and observed when conducting such research are outlined below.

(A) Recombinant DNA Molecules - The performing organization is required to comply with the guidelines established by the National

Institutes of Health entitled, Guidelines for Research Involving Recombinant DNA Molecules. In the event a project involving recombinant DNA or RNA molecules results in a grant award, a qualified Institutional Biosafety Committee must approve the research before funds will be released.

(B) Human Subjects at Risk - Regulations issued by the Department of Agriculture to be used in safeguarding the rights and welfare of human subjects used in research supported with USDA grant funds are contained in 45 CFR Part 46, and USDA regulations set forth in 7 CFR part 1c. All nonexempt research projects involving human subjects must be approved by an Institutional Review Board prior to commencing actual substantive work.

(C) Animal Care - The performing organization must comply with the Animal Welfare Act (7 U.S.C., 2131-2156); Public Law 89-544, 1996, and the regulations issued by the Department of Agriculture in 9 CFR parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the grantee must adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Sciences Societies, 1999. In the event a project involving the use of living vertebrate animals results in a grant award, funds will be released only after a qualified Institutional Animal Care and Use Committee has approved the project.

5.9 Grantee Commitments

Upon issuance of a research grant by USDA, the awardee will be required to make certain legal commitments through acceptance of the award document and the terms and conditions attached thereto, as well as any project-specific terms or conditions outlined. Most of these terms and conditions are contained in USDA's Uniform Federal Assistance Regulations, 7 CFR Part 3015, which will be incorporated into all Phase I awards resulting from this program solicitation and will be mailed in the package of materials when the research grant is forwarded to the awardee for acceptance. These regulations primarily consolidate internal policies and procedures relating to USDA's assistance programs and implement various Federally issued assistance policies, including applicable Federal cost principles and uniform

administrative requirements. Advance copies of these regulations are available upon request.

5.10 Additional Information

(A) This program solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, the terms of the funding agreement are controlling.

(B) Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and financial information to assure responsibility of the applicant, including certification that the proposing organization is in compliance with the Civil Rights Act of 1964. Form CSREES-666 (both sides) should be completed to provide the necessary organizational information, and Form CSREES-665 should be used to certify compliance with Title VI of the Civil Rights Act of 1964. (If portions of the information requested on Form CSREES-666 are not applicable to the proposing organization or entity, "N/A" should be written in the space provided.) These forms will be provided to the small business concern by the Office of Extramural Programs, CSREES, prior to the forwarding of the funding agreement for acceptance. The information contained in both forms must normally be submitted on a one-time basis only. (If sufficient changes occur within the organization to warrant submission of new or additional information, additional forms should be requested by calling (202) 401-5050.) It is anticipated that all Phase I awardees will be required to submit the above information, but Phase II awardees will be concerned primarily with submitting new forms only if they have undergone significant changes in organization, personnel, finance, or policies including those relating to civil rights. Phase II awardees will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statement or balance sheet).

(C) If an applicant or a grantee is contemplating any type of transaction involving the entity (i.e., merger, spin-off, or sale), it is advised that the applicant or the grantee contact the Director of the SBIR program for knowledge of how the

transaction may affect a potential grant or the grant, as applicable.

- (D) USDA is not responsible for any monies expended by the applicant prior to the award of any funding agreement.
- (E) This program solicitation is not an offer by USDA and does not obligate USDA to make any specific number of awards. Also, awards under this program are contingent upon the availability of funds.
- (F) Unsolicited proposals will not be accepted under the SBIR program in either Phase I or Phase II.
- (G) If an award is made pursuant to a proposal submitted under this SBIR Program solicitation, a representative of the contractor or grantee or party to a cooperative agreement will be required to certify that the concern has not previously been, nor is currently being, paid for essentially equivalent work by any Federal agency.

5.11 Certifications

- (A) Instructions for Statement as to Delinquency on Federal Debts by Applicants for Federal Assistance - Pursuant to OMB Circular A-129, (implemented by USDA in 7 CFR Part 3), “Except where required by law or approved by the head of the agency, no award of Federal funds shall be made to an applicant who is delinquent on a Federal debt until the delinquent account is made current or satisfactory arrangements are made between affected agencies and the debtor.” The certification of non-delinquency applies only to the organization requesting financial assistance and not to the individual project manager. By indicating “no” for item 8, Form CSREES-667, Proposal Cover Sheet, the applicant is providing the statement of non-delinquency on any Federal debt. For the purposes of this statement, the following definitions of delinquency apply:

- (1) Direct loans - a debt more than 31 days past due on a scheduled payment.
- (2) Grants - recipients of a “Notice of Grants Cost Disallowance” who have not repaid the disallowed amount or who have not resolved the disallowance.
- (3) Guaranteed and insured loans - recipients of a loan guaranteed by the Federal

Government that the Federal Government has repurchased from a lender because the borrower breached the loan agreement and is in default.

Examples of debts include delinquent taxes, audit disallowances, guaranteed and direct student loans, housing loans, farm loans, business loans, Department of Education institutional loans, benefit overpayments and other miscellaneous administrative debts.

NOTE: An applicant answering “Yes” to this question on Form CSREES-667 must attach explanatory information detailing all relevant particulars concerning the Federal debt.

- (B) Certifications Regarding Drug-Free Workplace Requirements (Grants) - These certifications are required by 7 CFR Part 3017, implementing the Drug-Free Workplace Act of 1988, 41 U.S.C. 701 et seq. Copies of the regulations may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Drug-Free Workplace Requirements, Alternative I, For Grantees Other Than Individuals

The grantee certifies that it will or will continue to provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee’s workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing an ongoing drug-free awareness program to inform employees about—
 - (1) The dangers of drug abuse in the workplace;
 - (2) The grantee’s policy of maintaining a drug-free workplace;
 - (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
 - (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—
 - (1) Abide by the terms of the statement; and
 - (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
- (f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—
 - (1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 et seq.; or
 - (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
- (g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Certification Regarding Drug-Free Workplace Requirements, Alternative II, For Grantees Who Are Individuals

- (a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant.
- (b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to the grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

Instructions for Certification of Drug-Free Workplace Requirements

1. By signing Form CSREES-667, the grantee is providing the certification set forth above.
2. The certification is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.
3. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.
4. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in

operation, State employees in each local unemployment office, performers in concert halls or radio studios).

5. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph three).
6. Definitions of terms in the Non-procurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation at 21 CFR 1308.11 through 1308.15;

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) all "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of sub-recipients or subcontractors in covered workplaces).

- (C) Debarment or Suspension Requirements - Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions, and Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048).

These certifications are required by the regulations implementing Executive Order 12549, Debarment and Suspension, 7 CFR 3017.510, Participants' responsibilities. Copies of the regulation may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048)

Form AD-1048 containing certification for each lower tier covered transaction will be sent to each Phase I and Phase II grantee at the time of award with the award letter. It should not be submitted to CSREES but should be maintained by the applicant with the other records relating to the award project.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions

- (1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
 - (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
 - (b) have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or Local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
 - (c) are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or Local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and
 - (d) have not within a three-year period preceding this application/proposal had one

or more public transactions (Federal, State or Local) terminated for cause or default.

- (2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Instructions on Certification Regarding Debarment and Suspension

1. By signing Form CSREES-667, the prospective primary participant is providing the certification for primary covered transactions set forth above.
2. The inability of a person to provide the certification will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.
4. The prospective primary participant shall provide immediate written notice to the Authorized Departmental Officer in accordance with 7 CFR Part 3017.510 (c) if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meaning set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may

contact CSREES for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by certification that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.
7. The prospective primary participant further agrees by certification that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions," from Form AD-1048, provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant will require its prospective lower tier participants to provide immediately written notice to the applicant if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Non-procurement List. As used herein, lower tier covered transactions generally include:
 - a. Any transaction (other than a procurement contract) for goods and services, regardless of type;
 - b. Any procurement contract for goods and services, regardless of type, that is expected to equal or exceed the Federal cap on small purchases (currently, \$100,000); and
 - c. Any procurement contract for goods and services, regardless of amount, under which the recipient will have a critical influence on or substantive control over the covered transaction (i.e., project manager and

providers of federally required audit services).

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

(D) Notice to Applicants - Certification/Disclosure Requirements Related to Lobbying - Section 319 of Public Law 101-121 (31 U.S.C. 1352), imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans. Certain provisions of the law also apply to Federal commitments for loan guarantees and insurance; however, it provides exemptions for Indian tribes and tribal organizations.

Current and prospective recipients (and their sub-tier contractors and/or sub-grantees) are prohibited from using Federal funds, other than profits from a Federal contract, for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement or loan. In addition, for each award action in excess of \$100,000 (or \$150,000 for loans) on or after December 23, 1989, the law requires recipients and their sub-tier contractors and/or sub-grantees to: (1) certify that they have neither used nor will use any appropriated funds for payment to lobbyists, (2) disclose the name, address, payment details, and purpose of any agreements with lobbyists whom recipients or their sub-tier contractors or sub-grantees will pay with profits or **non-appropriated** funds on or after December 23, 1989; and (3) file quarterly updates

about the use of lobbyists if material changes occur in their use. The law establishes civil penalties for noncompliance.

USDA, CSREES regulations implementing Section 319 of Public Law 101-121 are at 7 CFR Part 3018. Copies of 7 CFR Part 3018 may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Lobbying - Contracts, Grants, Loans, and Cooperative Agreements - In signing Form CSREES-667, the applicant certifies, to the best of his or her knowledge and belief, that:

1. No Federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal Loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan or cooperative agreement;
2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a Federal contract, grant, loan, or cooperative agreement, the applicant shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;
3. The applicant shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required

certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

(E) Compliance with the National Environmental Policy Act (NEPA) - As outlined in 7 CFR Part 3407 (the CSREES regulations implementing NEPA), the environmental data or documentation for any proposed project is to be provided to CSREES in order to assist CSREES in carrying out its responsibilities under NEPA. In some cases, however, the preparation of environmental data may not be required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA (e.g., preparation

of an environmental assessment (EA) or environmental impact statement (EIS)), pertinent information regarding the possible environmental impacts of a proposed project is necessary; therefore, the National Environmental Policy Act Exclusions Form (Form CSREES-2006) provided must be included in the proposal indicating whether the applicant is of the opinion that the project falls within one or more of the categorical exclusions. Form CSREES-2006 should be included at the end of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an EA or an EIS is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

6.0 SUBMISSION OF PROPOSALS

6.1 When to Submit

All Phase I proposals must be RECEIVED at USDA by close of business (COB) on August 31, 2004 (5:00 p.m. Eastern Time). Proposals received after this deadline will not be considered for funding.

All Phase II proposals must be received at USDA by COB on February 3, 2005. Proposals received after this deadline will not be considered for funding.

Only those small businesses previously receiving Phase I awards in either fiscal years 2003 or 2004 are eligible to submit Phase II proposals in fiscal year 2005. The SBIR Program Director will send a letter to all eligible Phase I awardees requesting Phase II proposals.

For the convenience of all potential applicants, the following schedule is provided for informational purposes:

Phase I

Deadline date.....August 31, 2004

Period of research
performance.....May 1, 2005 through
December 31, 2005

Final report due at USDA.....January 31, 2006

Phase II

Deadline date.....February 3, 2005

Beginning period of research performance --
approximately.....September 1, 2005

6.2 What to Submit

Applicants under both Phase I and Phase II are requested to submit an **original and 15 copies** of all proposals. These proposals must contain all of the information, **arranged in the same order**, as that outlined in section 3.0.

Note: CSREES does not accept proposals sent via facsimile or e-mail.

6.3 Where to Submit

Applicants are strongly encouraged to submit proposals via overnight mail or delivery service to ensure timely receipt by USDA. The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is:

SBIR Program c/o Proposal Services Unit Cooperative State Research, Education, and Extension Service U.S. Department of Agriculture Room 1420, Waterfront Centre 800 9th Street, S.W.

Washington, D.C. 20024

Telephone: (202) 401-5048

Proposals sent via the U.S. Postal Service must be sent to the following address:

SBIR Program c/o Proposal Services Unit Cooperative State Research, Education, and Extension Service U.S. Department of Agriculture, STOP 2245 1400 Independence Avenue, S.W. Washington, D.C. 20250-2245

6.4 Acknowledgment of Proposals

The receipt of proposals will be acknowledged by e-mail. Therefore, applicants are encouraged to provide e-mail addresses, where designated, on the Proposal Cover Sheet, Form CSREES-667. If the applicant's e-mail address is not indicated, CSREES will acknowledge receipt of the proposal by letter. If the applicant does not receive an acknowledgment within 60 days of the submission deadline, please contact the SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

6.5 Bindings

Do not use special bindings or covers on proposals submitted in response to this program solicitation. Staple all pages together securely in the upper left-hand corner of each copy of each proposal.

6.6 Packaging

If possible, the original and all copies of each proposal should be mailed in one package. Due to the volume of proposals received, applications submitted in several packages are very difficult to identify and track. If it becomes necessary to mail copies of a proposal in more than one package, the number of packages should be marked on the outside of each. It is important that **all packages be mailed at the same time.**

6.7 Questions Pertaining to the USDA SBIR Program or to this Solicitation

Written or verbal questions of a general nature about the USDA SBIR program, as well as general questions pertaining to this solicitation (but not pertaining to requests for additional copies of the solicitation), should be directed to the SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

6.8 Requests for Additional Copies of this Solicitation

Please note that this Program Solicitation is available through the USDA CSREES web page, www.csrees.usda.gov/funding/sbir/sbir.html. CSREES encourages the use of the electronic document. However, if necessary, paper copies of this solicitation may be ordered by writing to the U.S. Postal Service address shown in subsection 6.3 or by calling (202) 401-5048.

These materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and phone number to psb@csrees.usda.gov which states that you want a copy of the application materials for the Fiscal Year 2005 Small Business Innovation Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

6.9 Information on Proposal Status

It is anticipated that the evaluation of Phase I proposals will require approximately 6 months from August 31, 2004, and no information on proposal status will be available until final selections have been made. Both successful and unsuccessful applicants will be notified of final award decisions within approximately 6 months.

Evaluation of **Phase II** proposals will require approximately four months from February 3, 2005. Again, applicants are discouraged from making inquiries regarding the status of their proposals. All proposing organizations will be notified of final award decisions within approximately 4 months.

7.0 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Listed below are some of the sources that can provide technology search and document services which may be useful in preparing SBIR proposals. They can be contacted directly for service and cost information.

National Agricultural Library
Service Desk
U.S. Department of Agriculture
10301 Baltimore Avenue
Beltsville, Maryland 20705-2351
(301) 504-5755

National Technology Transfer Center
Wheeling Jesuit University
316 Washington Avenue
Wheeling, West Virginia 26003
(304) 243-2455 or (800) 678-6882

National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161
(800) 553-6847

Center for Technology Commercialization
1400 Computer Drive
Westborough, Massachusetts 01581-5043
(508) 870-0042

Great Lakes Industrial Technology Center
25000 Great Northern Corporate Center, Suite 260
Cleveland, Ohio 44070
(440) 734-0094

Mid-Atlantic Technology Applications Center
University of Pittsburgh
3400 Forbes Avenue, Eureka Bldg., 5th Floor
Pittsburgh, Pennsylvania 15260
(412) 383-2500

Mid Continent Technology Transfer Center
Texas Engineering Extension Service
The Texas A&M University System
College Station, Texas 77840
(979) 845-8762

NERAC, Inc.
One Technology Drive
Tolland, Connecticut 06084-3900
(860) 872-7000

Rural Enterprises, Inc.
2912 Enterprise Blvd.
Durant, Oklahoma 74702
(580) 924-5094

Sciencewise
300 Professional Drive, Suite 200
Gaithersburg, Maryland 20879
(301) 975-0103

Southern Technology Applications Center
College of Engineering
University of Florida
1900 SW 34th Street
Gainesville, Florida 32608
(352) 294-7822

8.0 RESEARCH TOPIC DESCRIPTIONS

SBIR proposals are solicited from a full range of topic areas. Specific subtopics are listed only as **examples** of advanced applications or basic research of interest to USDA and are **not to be interpreted as exclusive**. It is USDA's intention to provide sufficient flexibility to obtain the greatest degree of creativity and innovation possible, consistent with overall SBIR and USDA program objectives. USDA reserves the right to shift proposals to a more appropriate topic area when necessary for adequate review.

Proposals are encouraged that focus on problems dealing with bioterrorism, homeland security of rural communities, and agriculturally-related manufacturing technology.

8.1 Forests and Related Resources

Investigators are encouraged to contact Dr. Charles Cleland, National Program Leader at (202) 401-6852 regarding questions about the suitability of research

topics (or at cceleland@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this topic is to develop environmentally sound techniques to increase productivity of forest land and to increase the utilization of materials and resources from forest lands. These areas deal with (1) increasing growth and yield through improving planting stock, reducing pathogens and insects, improving the soil or reducing harvesting impacts, and developing means to ensure survival of newly planted trees; (2) increasing the utility of the material grown in the forest through improving lumber yield from trees, utilizing greater percentages of trees, and using residues from forest and wood manufacturing systems; (3) reducing ecological damage from forest operations; (4) reducing the risk of and controlling wildfire on forest land; and (5) developing new products or technologies to increase the use of wood.

(B) Suggested Subtopics

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) Growth and yield

Improving growing stock, tissue culture, genetic manipulation or vegetative reproduction of forest trees and other means of increasing the regenerative abilities of forests.

Reducing pathogens and insects - The volume of material lost to disease and insects exceeds that used for lumber and associated wood products. Subjects applicable here are those that reduce the impact of destructive agents.

Improving soil or reducing harvesting impacts - The fixing of nitrogen by symbiotic agents through genetic manipulation or by mycorrhizae to increase forest productivity through nitrogen enrichment of forest soils; research to reduce soil erosion, compaction, or other alterations caused by harvesting or forest operations (that is, physical improvement of forest soils).

Developing systems to increase the survival of newly planted trees through mechanical, physical, or chemical means that are environmentally safe.

(2) Increasing the utility of forest-grown material

Improving lumber yield or other means of increasing the volume and worth of wood from individual trees.

Utilizing a greater percentage of the tree through improved or new techniques of veneering or comminution, for the production of new or improved reconstituted products.

(3) Reducing ecological damage by forest operations

Research which provides for the economic recovery of resources from forests while raising potential productivity and reducing impacts to the ecological structure of the area of operation.

(4) Developing technology that facilitates the control of wildfires on forest lands

Research that provides systems for detecting and managing wildfires; systems for reducing fuel loads in forests; tools and equipment for improving the efficacy and safety of fire fighters on the ground and in the air; communication and navigation systems for improving the coordination of fire management activities.

(5) Developing new products or technologies to increase the use of wood

Products using wood as a basic component of systems to replace or compete with construction materials or techniques.

8.2 Plant Production and Protection

Investigators are encouraged to contact Dr. William Goldner, National Program Leader at (202) 401-1719 regarding questions about the suitability of research topics (or at wgoldner@csrees.usda.gov to arrange a telephone consultation).

Proposals submitted to this topic area will be divided between two review panels, one dealing with biological approaches, and the other dealing with engineering approaches.

Biological Approaches

(A) Scope of Research

The objective of this topic is to examine means of enhancing crop production by reducing the impact of harmful agents, enhancing the impact of new methods of

plant manipulation, and developing new crop plants and new uses for existing crops.

(B) Suggested Subtopics

Examples of research activities that would be appropriate for small business concerns include, but are not limited to, the following:

- (1) Plant improvement** - Improving the efficiency of crop production by utilizing innovative methods such as those of biotechnology, molecular biology, genomics, tissue culture, and embryogenesis to produce crops with improved quality, yield and agronomic or horticultural traits.
- (2) New crops** - Developing new crop plants (both terrestrial and aquatic) as sources of food, fiber or industrial products.
- (3) Plant protection** - Reducing the impact of plant pathogens, insect pests, and abiotic stress on crop plants; increasing plant resistance to plant pathogens, insect pests, and abiotic stress.

Engineering Approaches

(A) Scope of Research

The objective of this topic is to examine means of enhancing crop production by reducing the impact of harmful agents and developing effective crop production systems that are economically and environmentally sound.

(B) Suggested Subtopics

Examples of research activities that would be appropriate for small business concerns include, but are not limited to, the following:

- (1) Improved crop production methods or strategies** - Enhancing the efficiency of crop production by utilizing innovative methods and equipment for planting, growing and harvesting crop plants, including optimization of inputs and reduction of environmental impacts by implementing the use of precision farming technology, sensors, information technology, and remote sensing.
- (2) Plant protection** - Reducing the impact of plant pathogens, insect pests and competing

vegetation on crop plants by developing efficient and environmentally safe pesticide and herbicide usage equipment.

- (3) Energy conservation** - Developing crop management systems, farm and greenhouse structures, and waste utilization strategies for efficient use of energy.

8.3 Animal Production and Protection

Investigators are encouraged to contact Dr. Peter Burfening, National Program Leader at (202) 401-5823 regarding questions about the suitability of research topics (or at pburfening@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The overall objective of this topic area is to develop knowledge that will enable producers of food animals to increase production efficiency and to assure a reliable, safe supply of animal protein and other animal products while conserving resources and reducing costs of production. Some examples of the areas of research to be supported are: clarification of the nutritional requirements of food animals for improved growth and feed efficiency; determination of hormonal and cellular mechanisms which control reproduction; clarification of genetic processes that result in food animals with superior characteristics; and diagnosis, treatment and control of food animal diseases, parasites and other animal health hazards.

Proposals dealing with animal waste management should be submitted to topic area 8.11 and not this topic area.

(B) Suggested Subtopics

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) Animal Production

- (a) Animal nutrition and digestive physiology** - Research directed at understanding the interrelationships between alimentary microbial ecosystems, digestive processes, and the host animal, and providing nutritional characterization of feedstuffs and integrated nutrient management to enhance production efficiency.

- (b) **Animal reproduction** - Research on the control of estrus, ovulation and fertilization; enhanced embryo survival and development; enhanced parturition and perinatal survival; and advances in embryo technology such as sex control, twinning, frozen embryos and cloning.
- (c) **Animal genetics and breeding** - Studies aimed at germplasm improvement in food animals that will provide animals with superior characteristics in areas such as reproduction, growth and development, lactation and egg production, lean-to-fat ratios, and disease resistance. These studies may employ innovative application of traditional methods, or incorporate novel biotechnological approaches, including, but not limited to cell and tissue culture, molecular biology, and genomics.
- (d) **Livestock management systems** - Development of systems or processes that can be applied to food animal production enterprises that will provide greater efficiency in the production .

(2)Animal Protection

- (a) **Diagnostic tests** - Development of diagnostic tests for specific diseases and agricultural chemicals which pose a health hazard to food animals and a residue problem in animal food products.
- (b) **Therapeutic methods** - Treatment or treatment methods for acute or chronic health problems of food animals caused by specific infectious or non-infectious agents, parasites, chemicals and toxic agents, poisonous plants, injuries and other animal health hazards.
- (c) **Immunization methods** - Vaccines, bacterins or other methods to establish or enhance resistance of food animals to infectious diseases and parasites.
- (d) **Pest control strategies** - Development of alternative pest control or eradication methods so as to limit the use of and dependence on biotoxic substances. Such alternatives may include biological methods, sterile male techniques, artificial pheromones, and similar strategies.
- (e) **Preventive management** - Development of management methods designed to protect food animals against health hazards.
- (f) **Animal health costs** - Development of methodologies to accurately assess economic losses to animal health hazards and to measure

economic benefits of alternative methods of prevention and control.

8.4 Air, Water, and Soils

Investigators are encouraged to contact Dr. Charles Cleland, National Program Leader at (202) 401-6852 regarding questions about the suitability of research topics (or at ccleland@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to develop technologies for conserving and protecting air, water, and soil resources while sustaining optimal farm and forest productivity and the manufacture of resulting agricultural commodities.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) **Air Resources** - Development of innovative, energy-efficient, cost-effective products, processes, or services that optimize: **reduced soil erosion** by wind; **monitoring air quality**; **abatement of air pollution** stemming from agricultural and forestry enterprises (pollution from animal waste management systems is addressed in Topic Area 8.11); **wind utilization** for agricultural purposes.
- (2) **Water Resources** - Development of innovative, energy-efficient, cost effective products, processes, or services that optimize: **water conservation**, monitoring, restoration and maintenance of **water quality**, (pollution from animal waste management systems is addressed in Topic Area 8.11), and proper **irrigation** usage to meet current and future agricultural and forestry needs.
- (3) **Soil Resources** - Development of innovative, energy-efficient, cost-effective products, processes, or services that minimize the **loss of soil and soil nutrients or alteration of the physical and chemical nature of soil**; and technologies that **enhance soil properties**

while restricting environmental perturbation.

8.5 Food Science and Nutrition

Investigators are encouraged to contact Dr. Suresh Sureshwaran, National Program Leader at (202) 720-7536 regarding questions about the suitability of research topics (or at ssureshwaran@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objectives of food science and nutrition research programs are to develop new knowledge and a better understanding of the characteristics of the foods we eat and their nutritional impact; to apply new knowledge to improve our foods and our diets; and to systematically apply new knowledge to the production of useful new food products, processes, materials and systems, including application of nutritional information to consumer foods and food service systems.

(B) Suggested Subtopics

Research opportunities are many and varied. Areas appropriate for innovative research proposals from small business concerns might include, but not necessarily be limited to, the following:

- (1) Chemistry and biochemistry** - Novel or rapid assay or bioassay techniques for food constituents, nutrients, properties, or interactions. Quality control techniques or rapid methods for in-plant nutrient analyses are needed.
- (2) Microbiology and toxicology** - Rapid, efficient methods for determining presence of organisms and detecting the development of toxic metabolites, including systems for determining shelf-life and “pull date” of food items, are needed.
- (3) Processing** - Methods for automation of processes and tests; rapid analyses and cataloging of physical properties; processing parameters; package design; design of material, energy- and water-efficient processes for small industries; development of specialty products or processes; on-line monitoring and control of nutrient, ingredient, or additive levels.
- (4) Economics and statistics** - Improved sampling procedures for dry mixes; cost/benefit analyses;

and modeling systems, including distribution, warehousing and retailing systems.

- (5) Nutrition Education** - Developing and using information technology to convey important nutritional information and awareness to the public (e.g. obesity prevention).

8.6 Rural and Community Development

Investigators are encouraged to contact Dr. Suresh Sureshwaran, National Program Leader at (202) 720-7536 regarding questions about the suitability of research topics (or at ssureshwaran@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objectives of this research area are to foster, promote, or improve the well-being of rural Americans. This program supports research that will result in commercial products or services that are focused on issues and problems related to the economic development and social enhancement of rural areas, small towns, rural people, rural organizations, and rural institutions. Proposals submitted to this area should not concentrate primarily on the development of new technology, but rather on applying new or existing technology to address important issues and/or solving significant problems of importance to rural America. Proposals that involve development of new technology should explicitly discuss the specific rural problem or opportunity that will be examined, and how this technology will successfully address the problem or opportunity. The proposals do not need to be centered on agriculture, per se, but may be focused on any area (e.g., information systems, education, health care) that has the potential of providing significant benefits to rural Americans. Most of the competitive proposals submitted to this topic should include a market feasibility study as one of the research objectives.

(B) Suggested subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Income or Employment Opportunities**
Efforts are needed to foster or promote development of new and improved income or employment opportunities in rural areas. Topics may include products or services that enhance availability and capabilities of

entrepreneurs, promote innovative ways to organize production systems to increase efficiencies and profitability of rural firms, stimulate development of new agricultural enterprises to improve farm profitability, and development of new technologies to promote job creation and income growth in both the farm and non-farm sector of the rural economy.

(2) Service Delivery by Local Governments and Public Institutions

- Approaches are encouraged that will result in improvements in the service delivery capabilities of local governments and public institutions. Areas of interest include educational programs that address the specific needs of people in rural areas, new housing designs that enhance the availability, quality and affordability of rural housing, improved health care delivery systems for different segments of the rural population, information and managerial systems that improve the efficiency and effectiveness of local governments, and improvements in critical areas such as transportation, telecommunications, waste disposal and resource management.

(3) Sustainable and Resilient Communities

- Procedures are needed that will enhance homeland security by helping rural communities to become more sustainable and resilient when faced with unexpected natural or terrorist-caused disasters. Communities need to develop plans for dealing with disruptions in critical services, to strengthen emergency preparedness capability, to improve telecommunications and the information technology infrastructure, to educate members of the community on steps to take in case of a disaster, and to identify critical facilities that could be utilized in the event of an emergency.

(4) Farm Management and Efficiency

- Approaches are encouraged that will enable farmers to improve farm management efficiency and lead to improved farm profitability. Areas of interest include educational programs to teach farmers new management skills and new farming efficiencies, development of risk management

tools to facilitate better planning, development of improved farm labor management skills, new tools that will lead to improved farm safety, and new approaches that will encourage more efficient use of natural resources.

8.7 Aquaculture

Investigators are encouraged to contact Dr. Charles Cleland, National Program Leader at (202) 401-6852 regarding questions about the suitability of research topics (or at ccleland@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to enhance the knowledge and technology base necessary for the continued growth of the domestic aquaculture industry as a form of production agriculture. Emphasis is placed on research leading to improved production efficiency and increased competitiveness of private sector aquaculture in the United States. Studies on commercially important (or potentially important) species of fish, shellfish and plants, from both freshwater and marine environments, can be addressed.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to the following:

- (1) Reproductive Efficiency** - Novel or innovative approaches to improve reproductive efficiency in aquaculture including: greater control of maturation, ovulation, and fertilization; improved gamete and embryo storage; improved larval rearing techniques; enhanced reproductive performance of broodstock; and methods to control sex determination.
- (2) Genetic Improvement** - Novel or innovative approaches to improve production efficiency through genetic improvement of aquacultural stocks including: genetic mechanisms of sex determination; genetic basis for inheritance of commercially important traits such as growth, cold tolerance and pathogen susceptibility; identification of major genes affecting performance; application of molecular biology and genomics and the integration of this technology into breeding programs; basic gene structure and expression in aquatic species; performance evaluation of aquacultural stocks

and utilization of crossbreeding and hybridization.

- (3) **Integrated Aquatic Animal Health Management** - Novel or innovative approaches to reducing acute and chronic losses related to aquatic animal health in aquaculture production systems through an integrated holistic approach including: physiological stress related to the quality of the aquatic production system; genetic, environmental and nutritional components of aquatic health management; control of predation in aquaculture production systems; development of new vaccines or immunization procedures to enhance resistance to infectious diseases and parasites; development of diagnostic tests for specific diseases that pose a health hazard; and development of improved treatment methods for acute or chronic health problems caused by specific infectious or non-infectious agents, parasites, injuries, and chemical and toxic agents.
- (4) **Improved Production Systems and Management Strategies** - Novel or innovative approaches to improve existing or alternative production system design and management strategies including: development of biological, engineering and economic design criteria and models; enhancement of water quality in existing production systems through aeration, flow patterns, etc.; characterization, handling and treatment of effluent from aquacultural production systems; improved harvesting methods and strategies.

8.8 Industrial Applications

Investigators are encouraged to contact Dr. William Goldner, National Program Leader at (202) 401-1719 regarding questions about the suitability of research topics (or at wgoldner@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to promote the use of biobased products by developing new or improved technologies that will lead to increased production of industrial products from agricultural materials. This research will lead to new opportunities to diversify agriculture and enhance agriculture's role as a reliable supplier of raw materials to industry. Appropriate research areas are: development of new

crops that have the potential of producing raw materials that can be converted into useful industrial products; development of procedures for enhanced recovery of critical raw materials from agricultural commodities; development of improved technology for converting agriculturally derived raw materials into useful industrial products; and development of industrial products derived from agricultural materials to make them more effective and/or more cost competitive with non-agriculturally derived industrial products.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) **Oils and Lubricants** - Development of new agricultural sources of industrial oils and waxes for use as lubricants, cosmetics, soaps and detergents, plastics, paints, and many types of coatings.
- (2) **Natural Rubber** - Improved technology for the production of resin and improvement in the quality of the natural rubber, and research into new applications for bagasse and other co-products.
- (3) **Fuels** - New and improved technology for conversion of agriculturally important biomass material into alcohol and other products to be used as fuel additives and fuel substitutes.
- (4) **Chemicals from Starch** - Development of new products such as absorbants and specialty chemicals from corn and other starchy crops.
- (5) **Fibers** - New and improved technology for production of fiber from kenaf and other promising new fiber crops.

8.9 Marketing and Trade

Investigators are encouraged to contact Dr. Suresh Sureshwaran, National Program Leader at (202) 720-7536 regarding questions about the suitability of research topics (or at ssureshwaran@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to identify an array of innovative marketing strategies to increase sales of agricultural, forestry, and aquacultural products (raw commodities, plus processed, value-

added food, feed, and industrial products derived from these commodities), both domestically and abroad. This research will assess and evaluate the type, size, and location of market opportunities for specific U.S. products or categories of products; develop specific strategies to gain entry into these markets or expand sales in current markets for specific products or categories of products; identify barriers to trade and develop specific strategies that neutralize these barriers; develop advanced information systems that provide more complete, relevant and timely information relative to temporal marketing opportunities; and develop integrated management systems that would permit maximum efficiencies in assembling, handling, processing, packaging, transporting, and shipping products. Where appropriate, foreign travel may be approved provided justification is adequately documented in the proposal.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Development of Marketing Systems** - Develop post harvest, integrated management systems that take raw, partially processed, or fully processed products and improves the efficiency in assembling, packing, processing, and shipping products to “niche,” regional, national, and international markets. Included in this subtopic would be the development of methods that define strategies to: (a) better integrate collection/assembly systems, (b) minimize seasonal variations in production and processing levels; (c) improve product characteristics through the use of such systems; and, (d) design more efficient packaging, storing, and transportation systems, including intermodal systems.
- (2) Development of Innovative Real-Time/Near Real-Time Information Systems** - Develop current and projected economic information on product sales, potential demand, prices, quality standards and specifications, varietal and packaging preferences, and relevant time periods in either real-time, or near-real-time to enable firms to respond more rapidly to national and international marketing opportunities. Also involved in this subtopic would be innovative information products that can inform businesses of the availability, features, and economics of

new technologies and innovations, preferably using electronic media with interactive features.

- (3) Assessments and specification of marketing opportunities** - Identify new national and international markets, or the potential for increasing sales of U.S. forestry, agricultural, and aquacultural products in these markets. Quantify to the extent possible, market characteristics determining demand, product demand, and market structure; other changes relative to consumption patterns at home and abroad; shifts in retail and wholesale marketing; shifts in food manufacturing; and other changes that are relevant to successful marketing.

8.10 Wildlife

Investigators are encouraged to contact Dr. Peter Burfening, National Program Leader at (202) 401-5823 regarding questions about the suitability of research topics (or at pburfening@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to develop new or improved technologies and environmentally sound approaches for improved management of wildlife that will reduce the adverse impact of wildlife on agriculture and people and enhance the sustainability of wildlife populations. This program will focus on wildlife in terrestrial (including birds), freshwater and estuarine environments, but not the marine environment. This will include both the influence of wildlife on agriculture and the influence of agriculture on wildlife.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Wildlife Control** - Improved control methods for mitigating the influence of animals on crop plants, ornamental plants, livestock and aquaculture species are needed. Emphasis should be placed on development of non-lethal approaches to address wildlife control problems.
- (2) Wildlife Management** - Development of methods and approaches for improved management of wildlife populations are needed. The emphasis should be on maintaining the

sustainability of wildlife populations or improving the survivability of endangered species.

- (3) **Wildlife Reproduction and Health** - Improved methods for controlling wildlife populations in order to maintain them at sustainable levels are needed. Research is also needed on vaccine development and other approaches for controlling the spread of diseases within wildlife populations or from wildlife to agricultural animals and people.
- (4) **Habitat Management** - Improved methods of habitat management that will enhance the sustainability of wildlife populations and reduce their impact on agriculture, human health and property are needed. These methods may include approaches to maintain healthy ecosystems as well as approaches for ecosystem restoration where this will have a beneficial impact on important wildlife species.

animal production systems on the environment by establishment of better ways to: (a) handle both liquid and solid animal wastes; (b) improve the efficiency of waste collection systems; (c) improve the effectiveness of waste lagoons; (d) to develop better methods for disposal of animal wastes in ways that do not adversely impact the environment.

- (2) **Air Pollution** - Development of methods for the abatement of air pollution stemming from animal waste management systems.
- (3) **Water Resources** - Development of innovative, energy-efficient, cost effective products, processes, or services to reduce the impact of animal wastes on surface and groundwater resources.
- (4) **Value-added Products** – Development of innovative ways to process animal wastes into value-added products.

8.11 Animal Waste Management

Investigators are encouraged to contact Dr. William Goldner, National Program Leader at (202) 401-1719 regarding questions about the suitability of research topics (or at wgoldner@csrees.usda.gov to arrange a telephone consultation).

(A) Scope of Research

The objective of this research area is to develop new or improved technologies and environmentally sound approaches for improved management of animal waste that will reduce the adverse impact of animal waste on the environment and people, and improve the economics of animal production by optimizing waste management technologies and creating value-added products derived from animal waste. This program will focus exclusively on terrestrial animal production (including poultry). Proposals dealing with aquacultural waste should be submitted to Topic Area 8.7.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) **Systems for Handling Animal Waste** – Development of methods to reduce the impact of

9.0 SUBMISSION FORMS AND CERTIFICATIONS

UNITED STATES DEPARTMENT OF AGRICULTURE
SMALL BUSINESS INNOVATION RESEARCH
SOLICITATION NO. USDA / 05-1 (OMB Approved 0524-0025)

Date Received	Phase I and Phase II Proposal Cover Sheet		Proposal No. (for USDA use only)				
SUBMITTED	Small Business Firm:						
	Mailing Address:						
Project Title:							
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> Topic No. and Area (check appropriate box; see Section 8.0) 8.1 Forests and Related Resources 8.2 Plant Production and Protection 8.3 Animal Production and Protection </td> <td style="width: 33%; vertical-align: top;"> 8.4 Air, Water and Soils 8.5 Food Science and Nutrition 8.6 Rural and Community Development 8.7 Aquaculture </td> <td style="width: 33%; vertical-align: top;"> 8.8 Industrial Applications 8.9 Marketing and Trade 8.10 Wildlife 8.11 Animal Waste Management </td> </tr> </table>					Topic No. and Area (check appropriate box; see Section 8.0) 8.1 Forests and Related Resources 8.2 Plant Production and Protection 8.3 Animal Production and Protection	8.4 Air, Water and Soils 8.5 Food Science and Nutrition 8.6 Rural and Community Development 8.7 Aquaculture	8.8 Industrial Applications 8.9 Marketing and Trade 8.10 Wildlife 8.11 Animal Waste Management
Topic No. and Area (check appropriate box; see Section 8.0) 8.1 Forests and Related Resources 8.2 Plant Production and Protection 8.3 Animal Production and Protection	8.4 Air, Water and Soils 8.5 Food Science and Nutrition 8.6 Rural and Community Development 8.7 Aquaculture	8.8 Industrial Applications 8.9 Marketing and Trade 8.10 Wildlife 8.11 Animal Waste Management					
Amount Requested: (\$)		Proposed Duration (Mos.):	Congressional District No.:	YES NO			
1. The above concern certifies that it meets the first two criteria of a small business concern as stated in this solicitation or that it will meet that definition at time of award. (See subsection 2.2).							
2. The above concern certifies that it qualifies as a socially and economically disadvantaged small business as defined in this solicitation (See subsection 2.4). (For statistical purposes only).							
3. The above concern certifies that it qualifies as a women-owned small business as defined in this solicitation (See subsection 2.5). (For statistical purposes only).							
4. The above concern certifies that the business concern qualifies as a HUBZone-owned small business concern and meets the definition as stated in the solicitation (See section 2.6). (For statistical purposes only).							
5. Is the above concern affiliated with another concern? If yes, list affiliated organization below.							
6. The above concern certifies that the Project Manager's primary employment (at least 51%) will be with proposing firm at the time of any resulting award and during the conduct of the proposed research (See subsection 2.2(C)).							
7. The above concern certifies a minimum of two-thirds of the research (phase I) or one-half the research (phase II) will be performed by this firm (See subsection 2.2(D)).							
8. Will you permit the Government to disclose the title and technical abstract page of your proposed project, plus the name, address, and telephone number of the corporate official of your firm, if your proposal does not result in an award, to entities that may be interested in contacting you for future information?							
9. Has the applicant and/or Project Manager submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? See section 3.3(k).							
10. Is the organization delinquent on any Federal Debt? (See subsection 5.11). (If yes, attach explanatory information).							
11. Will the work in this proposal involve recombinant DNA, living vertebrate animals, or human subjects? (If yes, complete Form CSREES-2008).							
12. Is this proposal a resubmission of a proposal submitted earlier to the USDA SBIR Program (See subsection 3.3(D)). If yes, list the proposal number _____.							
<p>By signing and submitting this proposal, the prospective grantee is providing the required certifications set forth in 7 CFR Part 3017, as amended, regarding Debarment and Suspension and Drug-Free Workplace; and 7 CFR Part 3018 regarding Lobbying. (Please read the Certifications and Instructions included in this solicitation before signing this form.) In addition, the prospective grantee certifies that the information contained herein is true and complete to the best of its knowledge and accepts as to any grant award, the obligation to comply with the terms and conditions of the Cooperative State Research, Education, and Extension Service in effect at the time of the award. *Submission of the Social Security Number is voluntary and will not affect the organization's eligibility for an award. However, it is an integral part of the CSREES information system and will assist in the processing of the proposal.</p>							
PROJECT MANAGER			AUTHORIZED ORGANIZATIONAL OFFICIAL				
Name and Title			Name and Title				
Address			Address				
E-mail			E-Mail				
Telephone No.	Fax No.		Telephone No.	Fax No.			
Signature	Date		Signature	Date			

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number for this information collection is 0524-0025. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

PROPRIETARY NOTICE (IF APPLICABLE, SEE SUBSECTION 5.4) [Check here _____ if applies.]

These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than the evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to the applicable laws. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages _____ of this proposal.

U. S. Department of Agriculture
SMALL BUSINESS INNOVATION RESEARCH

OMB Approved 0524-0025

PHASE I AND PHASE II PROJECT SUMMARY*

FOR USDA USE ONLY			
Program Office	Solicitation No.	Proposal No.	Topic No.
TO BE COMPLETED BY APPLICANT			
Name and Address of Firm		Name and Title of Project Manager(s)	
Title of Project (80-character maximum)			
Technical Abstract (200-word limit)			
Anticipated Results/Potential Commercial Applications of Research (100-word limit)			
Keywords to Identify Technology/Research Thrust/Commercial Application (8-word maximum)			

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0025. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and viewing the collection of information.

*The Project Summary must be suitable for publication by USDA in the event of an award. Do not include proprietary information on this page. Form CSREES-668 (2/2001)

UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039
Expires 03/31/2005

BUDGET

ORGANIZATION AND ADDRESS				USDA AWARD NO.			
PROJECT MANAGERS(S)				DURATION PROPOSED MONTHS: _____	DURATION PROPOSED MONTHS: _____ Funds Approved by CSREES (If different)	Non-Federal Proposed Cost- Sharing/Matching Funds (If required)	Non-federal Cost- Sharing/Matching Funds Approved by CSREES (If Different)
A. Salaries and Wages				CSREES-FUNDED WORK MONTHS			
1. No. Of Senior Personnel				Calendar	Academic	Summer	
a. ____ (Co)-PD(s)							
b. ____ Senior Associates.....							
2. No. of Other Personnel (Non-Faculty)							
a. ____ Research Associates/Postdoctorates							
b. ____ Other Professionals.....							
c. ____ Paraprofessionals.....							
d. ____ Graduate Students.....							
e. ____ Prebaccalaureate Students.....							
f. ____ Secretarial-Clerical.....							
g. ____ Technical, Shop and Other.....							
Total Salaries and Wages							
B. Fringe Benefits (If charged as Direct Costs)							
C. Total Salaries, Wages, and Fringe Benefits (A plus B)							
D. Nonexpendable Equipment (Attach supporting data. List items and dollar amounts for each item.)							
E. Materials and Supplies							
F. Travel							
G. Publication Costs/Page Charges							
H. Computer (ADPE) Costs							
I. All Other Direct Costs (In budget narrative, list items and dollar amounts, and provide supporting data for each item.)							
J. Total Direct Costs (C through I)							
K. F&A/Indirect Costs (If applicable, specify rate(s) and base(s) for on/off campus activity. Where both are involved, identify itemized costs included in on/off campus bases.)							
L. Total Direct and F&A/Indirect Costs (J plus K)							
M. Other							
N. Total Amount of This Request							
O. Carryover -- (If Applicable)Federal Funds: \$				Non-Federal funds: \$			
P. Cost-Sharing/Matching (Breakdown of total amounts shown on line N)				Total \$			
Cash (both Applicant and Third Party)							
Non-Cash Contributions (both Applicant and Third Party)							
NAME AND TITLE (Type or print)				SIGNATURE (required for revised budget only)		DATE	
Project Manager							
Authorized Organizational Representative							
Signature (for optional use)							

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average 1.00 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

ASSURANCE STATEMENT(S) – FOR RESEARCH PROJECTS

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational

Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

NOTE: Check appropriate statements, supplying additional information when necessary.

1. INSTITUTION	2. CSREES PROJECT NUMBER OR AWARD NUMBER (if known)
	3. PROJECT MANAGER(S)

4. TITLE OF PROJECT

A. BIOSAFETY OF RECOMBINANT DNA

Project does not involve recombinant DNA.

Project involves recombinant DNA and was either approved () or determined to be exempt () from the NIH Guidelines by an Institutional Biosafety Committee (IBC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS Guidelines for Research Involving Recombinant DNA Molecules, as revised.

B. CARE AND USE OF ANIMALS

Project does not involve vertebrate animals.

Project involves vertebrate animals and was approved by the Institutional Animal Care and Use Committee (IACUC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with the Animal Welfare Act (7 USC, 2131-2156), Public Law 89-544, 1996, as amended, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR Parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Science Societies, 1999.

C. PROTECTION OF HUMAN SUBJECTS

☒ Project does not involve human subjects.

Project involves human subjects and

Was approved by the Institutional Review Board (IRB) on _____ (Date). Performing Institution holds a Federalwide assurance number _____; if not, a Single Project Assurance is required.

☒ Is exempt based on exemption number _____.

Specific plans involving human subjects depend upon completion of survey instruments, prior animal studies, or development of material or procedures. No human subjects will be involved in research until approved by the IRB and a revised Form CSREES-2008 is submitted.

This performing organization agrees to assume primary responsibility for complying with the Federal Policy for Protection of Human Subjects as set forth in 45 CFR Part 46, 1991, as amended, and USDA regulations set forth in 7 CFR 1c, 1992. All nonexempt research involving human subjects must be approved and under continuing review by an IRB. If the performing organization submits a Single Project Assurance, supplemental information describing procedures to protect subjects from risks is required.

SIGNATURE OF AUTHORIZED ORGANIZATIONAL REPRESENTATIVE	TITLE	DATE
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According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .50 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CSREES-2008 (12/02/00)

Instructions for Completing Assurance Statements and Certifications of Protection from Research Risks

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

If a research proposal covers multiple projects in which experimental protocols vary, the AOR must provide documentation of certification, through multiple copies of Form CSREES-2008, by the appropriate committee(s) for each specific protocol utilized in the projects. Examples of multiple project/proposals may include large multi-faceted special grants, multi-institutional consortia, multi-state research projects and some large umbrella Hatch proposals.

Formula funded activities require a certification of action taken by appropriate committees, which necessitates inclusion of the date of the action; the designation of "pending" is not an option. The designation of "pending" may be inserted for other grant proposals in lieu of reporting a date of certification that an appropriate committee took action. However, a subsequent approval must be obtained, and a revised Form CSREES-2008 must be submitted before a final award can be made.

A. BIOSAFETY OF RECOMBINANT DNA

If the project involves the use of recombinant DNA molecules, the performing organization shall assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS, Guidelines for Research Involving Recombinant DNA Molecules, as revised:

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

This responsibility includes:

1. Ensuring that a standing Institutional Biosafety Committee (IBC) is maintained in accordance with Part IV of the NIH Guidelines and also ensuring that the research plan is reviewed and approved by the IBC prior to commencing substantive work under the project. Actions by the IBC must be documented in Section A of the Form CSREES-2008.
2. Registering with the IBC all experiments involving recombinant DNA molecules conducted with funds provided under the project and complying with the containment requirements specified in Part III of the NIH Guidelines. Records of this research must be kept in a form that is available to CSREES upon request.

In addition, the funded recipient must report the following supplemental data to CSREES and to the reviewing IBC:

- a. New technical information relating to risks and safety procedures.
- b. Serious accidents or releases involving recombinant DNA.
- c. Serious illness of a laboratory worker which may be project related.
- d. Other safety problems.

The NIH Guide for Reporting the Occurrence of Serious Adverse Events is published at:

<http://grants2.nih.gov/grants/policy/recombinentdnaguidelines.htm>

IBC review and approval must be documented in Section A of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section A of the Assurance Form 2008 should not be older than 36 months.

B. CARE AND USE OF ANIMALS

The responsibility for the humane care and treatment of vertebrate animals used in any research project supported with CSREES funds rests with the performing organization. If a project involves animals, except farm animals used for food and fiber research, the personnel identified with the project, and the endorsing officials of the recipient's organization must comply with the Animal Welfare Act (AWA). The AWA (7 USC, 2131-2156; Public Law 89-544, 1996, as amended) and the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR Parts 1, 2, 3, and 4, and subsequent rules and regulations) pertain to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal awards:

<http://www.nal.usda.gov/awic/legislat/awicregs.htm>

In the case of laboratory animals used or intended for use in research, the institution shall adhere to the principles enunciated in the Guide for the Care and Use of Laboratory Animals, (ILAR, National Academy of Sciences); 1996:

<http://www.nap.edu/readingroom/books/labrats/>

and to the USDA regulations and standards issued under the public laws stated above. In case of a conflict between the guidelines, the higher standard shall be used.

When domesticated farm animals are used or intended for use in agricultural food and fiber production research, teaching or other activities and housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 1999:

<http://www.nal.usda.gov/awic/index.html>

which is available from the Federation of Animal Science Societies, 1111 N Dunlap, Savoy, IL 61874.

Prior to commencing research activities with vertebrate animals, all protocols involving animals in CSREES funded projects must be approved by the Institutional Animal Care and Use Committee (IACUC):

<http://grants2.nih.gov/grants/olaw/olaw.htm>

IACUC review and approval must be documented in Section B of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section B of the Assurance Form 2008 should not be older than 36 months.

C. PROTECTION OF HUMAN SUBJECTS

The performing organization is responsible for protecting the rights and welfare of any human subject involved in CSREES sponsored research and related activities. If a research project protocol involves the use of human subjects, the institution must agree to comply with the Department of Health and Human Services (DHHS) regulations on the protection of human subjects:

<http://ohrp.osophs.dhhs.gov/polasur.htm>

as set forth in 45 CFR Part 46, 1991, as amended (formally adopted as "The Common Rule"), and USDA regulations set forth in 7 CFR 1c, 1992. If a research project protocol involves the use of human subjects, one and only one of the three options outlined under section C of Assurance Form 2008 must be checked.

All nonexempt research protocols involving human subjects must be approved and undergo continuing review by an Institutional Review Board (IRB). If the performing organization qualifies for Federalwide Assurance (FWA) status and has been approved by the Office for Human Research Protections (OHRP), DHHS, then report the assurance number along with the approval date. A list of IRBs with FWA status is available at:

<http://ohrp.osophs.dhhs.gov/irbasur.htm>

If the performing organization does not have MPA status, a Single Project Assurance (SPA) form may be obtained from OHRP, HHS at:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/spa.htm>

and must be submitted. A SPA is a document to assure compliance and continuing review of the project being proposed, and it is limited in use and duration to this individual research activity. A SPA signed by the IRB Chairperson, AOR, and Project Manager of the research project must be submitted. Also, provide additional information regarding the recruitment and selection of subjects, the proposed processes of informed consent and maintenance of confidentiality, and risk and benefit assessments for review by CSREES staff. An institution submitting a SPA may utilize its own IRB or the IRB of a neighboring institution.

The IRB approval date should reflect a timely review. The date reported in section C of the Assurance Form 2008 should not be older than twelve months, because the “Common Rule” requires annual review.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, and any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk or be damaging.
3. Research not exempt in #2 may be exempt if, in the use of educational tests, the subjects are elected or appointed officials, or federal statutes require that confidentiality will be maintained.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
5. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

A complete explanation of these exemptions can be found at:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance>

A project may be funded but temporarily excused from IRB approval if specific protocols involving human subjects depend upon the development of survey instruments, procedures or materials, or completion of animal studies. However, human subjects may not be involved in research activities until IRB approval is obtained and a revised Form CSREES-2008 is submitted.

National Environmental Policy Act Exclusions Form

Project Manager Name	Institution
Address	

Under 7 CFR Part 3407 (CSREES's implementing regulations of the National Environmental Policy Act of 1969 (NEPA)), environmental data or documentation is required in order to assist CSREES in carrying out its responsibilities under NEPA, which includes determining whether the proposed activity requires the preparation of an environmental assessment or an environmental impact statement, or whether such activity can be excluded from this requirement on the basis of several categories. Therefore, it is necessary for the applicant to advise CSREES whether the proposed activity falls into one of the following Department of Agriculture or CSREES categorical exclusions, or whether the activity does not fall into one of these exclusions (in which case the preparation of an environmental assessment or an environmental impact statement may be required). Even though the applicant considers that a proposed project may or may not fall within a categorical exclusion, CSREES may determine that an environmental assessment or an environmental impact statement is necessary for a proposed project should substantial controversy on environmental grounds exist or if other extraordinary conditions or circumstances are present that may cause such activity to have a significant environmental effect.

Please Read All of the Following and Check All Which Apply

☐ **The proposed activity falls under the categorical exclusion(s) indicated below:**

Department of Agriculture Categorical Exclusions

(found at 7 CFR 1b.3 and restated at 7 CFR 3407.6 (a)(1)(i) through (vii))

- ☐ (i) Policy development, planning and implementation which are related to routine activities such as personnel, organizational changes, or similar administrative functions
- ☐ (ii) Activities that deal solely with the functions of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds
- ☐ (iii) Inventories, research activities, and studies such as resource inventories and routine data collection when such actions are clearly limited in context and intensity
- ☐ (iv) Educational and informational programs and activities
- ☐ (v) Civil and criminal law enforcement and investigative activities
- ☐ (vi) Activities that are advisory and consultative to other agencies and public and private entities, such as legal counseling and representation
- ☐ (vii) Activities related to trade representation and market development activities abroad

CSREES Categorical Exclusions

(found at 7 CFR 3407.6(a)(2)(i) through (ii))

The following categories of CSREES actions are excluded because they have been found to have limited scope and intensity and to have no significant individual or cumulative impacts on the quality of the human environment:

- ☐ (i) The following categories of research programs or projects of limited size and magnitude or with only short-term effects on the environment:
 - ☐ (A) Research conducted within any laboratory, greenhouse, or other contained facility where research practices and safeguards prevent environmental impacts
 - ☐ (B) Surveys, inventories, and similar studies that have limited context and minimal intensity in terms of changes in the environment
 - ☐ (C) Testing outside of the laboratory, such as in small isolated field plots, which involves the routine use of familiar chemicals or biological materials
- ☐ (ii) Routine renovation, rehabilitation, or revitalization of physical facilities, including the acquisition and installation of equipment, where such activity is limited in scope and intensity

OR

☐ **Proposed activity does not fall into one of the above categorical exclusions**

(NOTE: If checked, please attach an explanation of the potential environmental impacts of the proposed activity.

May require completion of an environmental assessment or an environmental impact statement.)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

10.0 SAMPLE PROPOSAL FROM USDA SBIR SOLICITATION

This proposal, which resulted in a Phase I award, was submitted under the Fiscal Year 1999 USDA SBIR Program Solicitation guidelines. The sample proposal is provided solely for general guidance. In the original proposal, the cover page was signed by both the project manager and authorized organizational official. The social security numbers and budget have been deleted to protect confidentiality.

Visit the web to see the sample proposal available only in PDF version at:

http://www.csrees.usda.gov/funding/sbir/sbir_sample.html

You may also put your mouse arrow over the address above, hold the control button and left click your mouse to go directly to the web page through your browser.